

INSTRUMENTOS DE AVALIAÇÃO DA DOR EM  
DOENTES COM ALTERAÇÃO DA CONCIÊNCIA:  
UMA REVISÃO SISTEMÁTICA

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CUNHA

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DISSERTAÇÃO DE MESTRADO APRESENTADA À FACULDADE DE MEDICINA DA UNIVERSIDADE DO PORTO PARA OBTENÇÃO DO GRAU DE MESTRE EM CUIDADOS PALIATIVOS, SOB ORIENTAÇÃO DO PROFESSOR DOUTOR FILIPE PEREIRA E CO-ORIENTAÇÃO DA MESTRE ANA LEONOR RIBEIRO.



BIOÉTICA

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UMA REVISÃO SISTEMÁTICA**

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Porto, 2011

## **Agradecimentos**

Ao Prof. Doutor Filipe Pereira pela competência científica e orientação, as recomendações, a cordialidade e a liberdade que me permitiu, sendo uma colaboração decisiva para que este trabalho contribuisse para o meu desenvolvimento pessoal.

À Mestre Ana Leonor Ribeiro pela simpatia, a forma como me recebeu, me incentivou e me encaminhou neste percurso. Agradeço a orientação, a disponibilidade, a sabedoria transmitida, o interesse, a frontalidade e o rumo que marca a pesquisa realizada.

Ao Prof. Doutor Rui Nunes pela compreensão, coordenação, e pelo inestimável apoio durante todo o curso.

Aos colegas de curso pelo companheirismo, em especial à Andreia Montenegro pela amizade e apoio.

À Álvora Silva á Inês Rocha pela amizade, colaboração e disponibilidade manifestada, e em especial à Rosa Silva pela paciência e pelo contributo numa fase difícil do percurso, manifestando entusiasmo pelo trabalho.

Aos meus pais por todo o orgulho que sempre manifestaram, por todo o incentivo e compreensão do tempo dedicado a este fim.

À minha irmã que apesar das ausências e falta de atenção sempre compreendeu com ternura, esperando que a seriedade e empenho que dedico ao trabalho lhe possa servir de estímulo para fazer sempre “mais e melhor”.

A todos aqueles que, de alguma forma, deram a sua contribuição para que este trabalho fosse realizado, aqui deixo o meu sincero agradecimento.

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## INTRODUÇÃO

A elaboração deste trabalho surge no seguimento da frequência do Mestrado em Cuidados Paliativos da Faculdade de Medicina da Universidade do Porto, que implica a apresentação à academia de um trabalho que demonstre, por parte do candidato, capacidades para desenvolver percursos de investigação compatíveis com o estatuto de mestre. Em paralelo, o referido trabalho constitui um documento de avaliação do segundo ano do referido curso.

Assim, o que se pretende com o documento apresentado, é a exposição de um percurso de investigação que revele conhecimentos na área em estudo e as capacidades para a prática de investigação, necessários à obtenção de grau de Mestre em Cuidados Paliativos.

Meleis (2010), autora que tomamos com referencial para o exercício profissional, refere que a primeira missão da enfermagem se relaciona com a prática, procurando o conhecimento das repostas humanas à saúde e doença, para ajudar os seres humanos a monitorizar e promover a saúde e, nesta perspectiva, o objectivo do desenvolvimento de conhecimento, por parte dos enfermeiros e da Enfermagem, é perceber as necessidades dos clientes, de forma a mobilizar terapêuticas de enfermagem significativas e efectivas.

Segundo Polit, Beck e Hungler (2004, p.20) “o desenvolvimento e a utilização do conhecimento são essenciais para a melhoria constante no atendimento ao paciente”, adoptando a prática baseada em evidências um papel central neste processo, no sentido de fundamentar tomadas de decisão e processos assistenciais mais proficientes.

Do mesmo modo, Fortin (2009, p.16) refere que “a aprendizagem da investigação deve estar ligada à prática, de forma que o profissional, no termo dos seus estudos, possa servir-se dos seus conhecimentos para definir problemas particulares a estudar”.

Actualmente, na área da saúde está em curso um modelo de transição de pensamento, no qual se valoriza a prática clínica baseada em evidências, em detrimento da decisão baseada “apenas” na experiência e realidades muito circunstanciadas. Neste paradigma, pesquisa e prática clínica não estão dissociadas e fazem parte de um processo sistemático e contínuo de auto-aprendizagem e auto-avaliação, sem o qual, as condutas se tornam rapidamente desactualizadas (Pereira e Bachion, 2006). Agregar evidências de pesquisa, para guiar a prática clínica, é uma das principais razões para se desenvolverem estudos que sintetizam a literatura (Sampaio e Mancini, 2007).

Enfermagem baseada em evidências ou cuidado baseado em evidências conduz a uma avaliação crítica sistemática das informações disponíveis, para a prática da tomada de decisão (baseada em evidências) significando, portanto, integrar a experiência clínica individual com a melhor evidência externa disponível oriunda da pesquisa sistemática (Pereira e Bachion, 2006).

Respondendo a esta necessidade de sintetizar o conhecimento produzido e de separar os estudos pertinentes daqueles irrelevantes, no contexto de determinada questão clínica, surge a necessidade de realizar revisões sistemáticas da literatura. Assim, “Revisão Sistemática da Literatura constitui uma revisão de estudos por meio de uma abordagem sistemática, utilizando metodologia claramente definida, buscando minimizar os erros nas conclusões” (Pereira e Bachion, 2006, p.492). Desta forma “pressupõe-se que, diferentes pesquisadores, ao seguirem os mesmos passos descritos, cheguem às mesmas conclusões”, contribuindo para a tomada de decisão baseada em evidência (Pereira e Bachion, 2006, p.492).

É neste quadro de referências, descrito ao longo dos parágrafos anteriores, que situamos a abordagem que fizemos à “dor” e em particular, à sua avaliação/ monitorização em doentes com alteração da consciência; realidade com a qual nos deparamos diariamente. Deste modo, o estudo delineado teve como principal objectivo, identificar e analisar o potencial de utilização clínica das escalas existentes para avaliação da dor em doentes com alteração da consciência.

Com o avanço da Medicina nas últimas décadas, assistimos a um aumento da esperança média de vida para mais de 70 anos. Embora as intervenções médicas sejam cada vez mais sofisticadas, a população, cada vez mais envelhecida é alvo do aparecimento de doenças crónicas de evolução progressiva às quais, muitas vezes, está associada a dependência de terceiros e a dor.

Face a este contexto, a Enfermagem, assim como outras profissões, tem vindo a especializar-se, de forma crescente, originando uma variedade, cada vez maior de áreas de actuação e definição de novos conceitos de saúde e doença.

Actualmente, a dor é um tema corrente e valorizado no âmbito do estudo das ciências médicas. Do mesmo modo, tem vindo a ser mais abordada/revelada, pelos *media* devido ao reconhecimento da sua especificidade: dor como doença e não apenas como sintoma, dor de difícil determinação, dor crónica, dor e sofrimento...

A origem etimológica da palavra dor demonstra a antiguidade da mesma. Etimologicamente, dor (*pain* em inglês) deriva de *poena*, que em latim significa *castigo*, e *paciente* deriva do latim *patior* o que aguenta ou suporta o sofrimento e a dor (Dias, 2009).

Ao longo da história a dor foi caracterizada de diferentes modos e compreendida à luz dos diferentes conceitos de saúde e doença vigentes.

Na década de 1960, a médica inglesa, Cecily Saunders introduziu o conceito de “Dor Total”, constituída por vários componentes: físico, mental, social e espiritual. Este conceito de Dor Total mostra a importância de todas essas dimensões do sofrimento humano. Assim, Saunders estabeleceu a importância de uma abordagem multidisciplinar e da presença de uma equipa interdisciplinar para que se obtenha o máximo sucesso no tratamento da pessoa (Dias, 2009).

Globalmente, a dor pode ser definida como uma sensação caracterizada por um conjunto de experiências perceptuais e emocionais desagradáveis desencadeantes de respostas autonómicas, psicológicas e somatomotoras com repercussões fisiológicas, emocionais, cognitivas e sociais (Seeley, 2001).

Assim, e sendo uma experiência multidimensional, exige / envolve na sua avaliação dois intervenientes fulcrais, a pessoa que a experiencia e o técnico de saúde que a avalia e, idealmente, alivia ou palia.

Fundada em 1973, a *International Association for the Study of Pain* (IASP) (Joint Commission, 2001), define a dor, como uma sensação ou experiência emocional desagradável, associada a um dano tecidual real ou potencial, ou descrito nos termos de tal dano. Esta definição, assumida também pela Direcção Geral de Saúde (2003), enfatiza a Dor como uma experiência complexa que inclui múltiplas dimensões, sendo que, a severidade da dor não é directamente proporcional à quantidade de tecido lesado e muitos factores podem influenciar a percepção deste sintoma. Aqui destacam-se, por exemplo: fadiga, depressão, emoções como raiva e medo, ansiedade e sentimentos de falta de esperança e amparo (Joint Commission, 2001). Por conseguinte, a Direcção-Geral de Saúde, na Circular Normativa n.º 9 de 14/06/2003, entende que “a Dor é um sintoma que acompanha, de forma transversal, a generalidade das situações patológicas que requerem cuidados de saúde; o controlo eficaz da Dor é um dever dos profissionais de saúde, um direito dos doentes que dela padecem e um passo fundamental para a efectiva humanização das Unidades de Saúde” (Direcção-Geral de Saúde, 2003, p.1). “O sucesso da estratégia terapêutica analgésica planeada depende da monitorização da Dor em todas as suas vertentes; a avaliação e registo da intensidade da Dor, pelos profissionais de saúde tem de ser feita de forma regular, à semelhança dos sinais vitais (...)” (Direcção-Geral de Saúde, 2003, p.1). Este aspecto é essencial, na medida em que, como sabemos, quanto maior é a qualidade do diagnóstico mais adequada será a abordagem terapêutica.

De acordo com a Ordem dos Enfermeiros (OE) Portugueses (2008, p.7), e “no âmbito das suas competências nos domínios da prática profissional, ética e legal do desenvolvimento profissional, o enfermeiro toma por foco de atenção a dor contribuindo para a satisfação do cliente, o bem-



estar e auto-cuidado (...), privilegiados pela proximidade e tempo de contacto, os enfermeiros encontram-se numa posição relevante para promover e intervir no controlo da dor”.

Em 2011, na Classificação Internacional para a Prática de Enfermagem – CIPE<sup>®</sup> versão 2.0 (Internacional Council of Nurses - ICN, 2011) o Conselho Internacional de Enfermeiros (ICN) define a dor como “aumento de sensação corporal desconfortável, referência subjectiva de sofrimento, expressão facial característica, alteração do tónus muscular, comportamento de autoprotecção, limitação do foco de atenção, alteração da percepção do tempo, fuga do contacto social, processo de pensamento comprometido, comportamento de distração, inquietação e perda de apetite”.

A humanização da dor e do sofrimento humano passam, para alguns autores, por uma profunda crise em que a vulnerabilidade da pessoa humana deixou de ser o centro das atenções (Pessini, 2002). Contudo, o que hoje sabemos acerca do fenómeno da dor e dos factores que a condicionam, na especificidade de cada ser humano, enfatiza que o que é realmente importante é valorizar a dor, tomá-la verdadeiramente como 5.º sinal vital. Assim, deve-se “avaliar e respeitar a avaliação que o outro faz, quando pode (pois que a intensidade da dor é a que a pessoa diz que é) e a que enfermeiro realiza por ele, quando o próprio não pode” (Ordem dos Enfermeiros, 2008, p.8).

Partindo da premissa que a prestação de cuidados de Enfermagem à pessoa com dor – pessoa em sofrimento – tem como finalidade a promoção do bem-estar, cabe ao enfermeiro avaliar, diagnosticar, planear e executar as intervenções necessárias, ajuizando resultados (Ordem dos Enfermeiros, 2008). Esta posição não coloca em causa a necessária colaboração multidisciplinar e profissional, na medida em que a perspectiva colaborativa, que fundamenta o exercício das equipas de saúde, se orienta para objectivos (em última análise) comuns.

Assim, o conceito de Dor tem vindo a avançar no sentido de admitir que a dor é uma experiência única e individual, modificada pelo conhecimento prévio de um dano que pode ser existente ou presumido (Ordem dos Enfermeiros, 2008). Esta perspectiva deriva dos trabalhos de McCaffery e Pasero (1999, p.15), que salientaram o auto-relato e o carácter subjectivo e pessoal da experiência da Dor, ao defini-la como sendo **“aquilo que a pessoa que a experiencia diz que é, existindo sempre que ela diz que existe”**.

A incorporação desta visão nalguns ambientes de cuidados afigura-se como problemática, em particular quando os doentes por múltiplos motivos, como as alterações da consciência, não estão competentes para “dizer o que é”. No entanto, a incapacidade / limitação de comunicação verbal

não nega a possibilidade de que um indivíduo está a sentir dor, o que implica a necessidade de instrumentos adequados para a avaliar e aliviar através do tratamento.

É pela preocupação suscitada pelas dificuldades de avaliação da dor em doentes com compromissos da consciência que este estudo visa identificar e analisar as escalas de avaliação da dor existentes e o seu potencial de utilização.

Na Classificação Internacional para a Prática de Enfermagem – CIPE<sup>®</sup> versão 2.0 (Internacional Council of Nurses - ICN, 2011), o Conselho Internacional de Enfermeiros, define consciência como “Resposta mental a impressões resultantes de uma combinação dos sentidos, mantendo a mente alerta e sensível ao ambiente exterior”.

A alteração subtil do estado de consciência, muitas vezes, surge como um dos primeiros sinais de compromisso neurológico, antes de serem evidentes outras alterações. O nível de consciência pode apresentar-se sob um estado de consciência total, de alerta e cooperação ou numa ausência total de reacção a qualquer estímulo externo (Baptista, 2003).

Uma vez que um dos maiores desafios consiste na monitorização eficiente da dor nos doentes com alteração da consciência, é possível concluir, a partir do anteriormente exposto, que a assistência ao doente com dor é complexa, exigindo tanto conhecimentos como habilidade da equipa assistente para a perceber e tratar.

Indo de encontro ao anteriormente exposto, o Plano Nacional de Saúde de 2004-2010, referia a Dor como um sintoma tradicionalmente negligenciado na nossa sociedade, que tem sido sub-diagnosticado e sub-tratado nos serviços de saúde, e que pela sua frequência possui “elevado potencial para causar sofrimento e gerar incapacidades (...)”, pelo que “constitui um importante problema da saúde pública que urge combater” (Ministério da Saúde Português, 2004, p.91).

A Ordem dos Enfermeiros com o objectivo de sublinhar a importância da avaliação e do alívio da dor como elementos centrais para o bem-estar e a qualidade de vida dos doentes, em 2008, no Dia Nacional de Luta Contra a Dor (14 de Junho), apresentou um documento orientador - Guia Orientador de Boa Prática - onde descreve a importância da avaliação da Dor como um padrão de qualidade na prestação de cuidados de enfermagem (Ordem dos Enfermeiros, 2008).

Neste contexto, o estudo aqui reportado pode ser entendido como um esforço que se inscreve na linha proposta pela OE, na medida em que tem por finalidade:

***Contribuir para a melhoria da qualidade das práticas de enfermagem, no contexto específico da problemática da assistência a pessoas com dor, através da criação de condições e orientações para a utilização de instrumentos válidos e precisos no***

***processo de avaliação e monitorização da experiência dolorosa de doentes com compromisso da consciência.***

Pretende-se, assim, através deste estudo que a dor, a sua avaliação e, por consequência, controlo sejam “valorizados e sistematicamente diagnosticados, avaliados e registados pelos profissionais de saúde (...) elevando o seu registo a categoria equiparada de sinal vital” (Direcção Geral de Saúde, 2003, p.4).

A problemática da dor é, sem dúvida alguma, um dos domínios em que a investigação e os trabalhos iluminados pela filosofia, princípios e orientações dos cuidados paliativos mais têm apostado. Assim e tendo como objectivo central a promoção do bem-estar e da qualidade de vida do doente, disponibilizando-se tudo aquilo que vá de encontro a essa finalidade, os cuidados paliativos são oferecidos com base nas necessidades do doente “promovendo uma abordagem global e holística do sofrimento” (Barbosa e Neto, 2010, p.3) destes.

A dor é um sintoma frequente e frequentemente associado a sofrimento, com elevado impacto na vida dos doentes, sendo que o objectivo final do processo de avaliação da dor é desenvolver uma estratégia de tratamento apropriada (Barbosa e Neto, 2010).

Neste quadro, o estudo aqui reportado situa-se no âmago do objecto e propósito do Curso de Mestrado que frequentamos na Faculdade de Medicina da Universidade do Porto.

## **1. O CONTROLO DA DOR - RELEVÂNCIA DO DIAGNÓSTICO DE ENFERMAGEM**

A tentativa de aumentar conhecimentos na área da fisiopatologia, semiologia e terapêutica da dor, cresceu exponencialmente, sobretudo a partir dos meados do século passado.

A dor continua a constituir uma dos principais problemas associados aos fenómenos de saúde/doença. Os enfermeiros são profissionais providos de competências e faculdades de exercício autónomo (Ordem dos Enfermeiros, 2008), mas que se articulam com os demais intervenientes no processo terapêutico (em particular, os médicos), tendo por horizonte um “bem comum”. O papel dos enfermeiros na equipa, desde sempre, esteve associado, entre outros aspectos, à vigilância dos doentes. Assim, a vigilância da dor e, por consequência, o seu controlo depende e é resultado do nível de proficiência dos cuidados de enfermagem neste domínio.

Segundo McCaffery e Beebe (1989), devemos acreditar que o controlo da dor é uma meta terapêutica legítima, que contribui significativamente para o bem-estar físico e emocional do paciente e que deve ser um dos itens prioritários do plano de cuidados.

Pimenta e Cruz (1998) citados por Rigotti e Ferreira (2005) referem que é importante determinar os elementos que possam justificar, manter ou exacerbar o quadro doloroso do doente e perceber o sofrimento e a incapacidade que este quadro pode causar, apurando o seu impacto na vida do indivíduo. Deste modo, é igualmente importante verificar a eficácia das intervenções terapêuticas instituídas no plano de cuidados individual do doente.

No sentido de explorar os dados relacionados com a avaliação da dor e os cuidados de enfermagem ao doente que dela padece, o estudo “Intervenções de enfermagem ao paciente com dor” de 2005, procedeu a revisão bibliográfica da literatura especializada e chegou à conclusão que a “dor é um fenómeno subestimado nos pacientes e neste sentido a educação em enfermagem necessita repensar a formação do enfermeiro” (Rigotti e Ferreira, 2005, p.50). Os autores do referido estudo acreditam ainda que a preparação dos enfermeiros para o controlo e monitorização da dor não está a ser eficaz e, relativamente ao défice de registos apurado, estes devem ser aperfeiçoados pois servem para comunicação entre profissionais, como fontes de pesquisa e base para auditorias. Desta forma, o estabelecimento e registo de um padrão de avaliação da dor do doente surgem como fundamentais para uma melhor assistência de

enfermagem (Rigotti e Ferreira, 2005). É neste contexto que se percebe a importância da utilização de instrumentos válidos e precisos para proceder à avaliação e monitorização “contínua” da dor.

É importante abordar a dor como um sintoma que afecta significativamente a qualidade de vida da pessoa, interferindo no seu bem-estar. Na mesma linha, o enfermeiro, enquanto profissional que se encontra na primeira linha de cuidados ao paciente, tem um papel fundamental no seu diagnóstico/ avaliação/ monitorização e controlo, elementos que se reportam como centrais para a obtenção de ganhos em saúde neste domínio.

Seguindo esta problemática, Fontes e Jaques (2007), ao investigarem acerca do papel de enfermagem em relação à monitorização da dor, através de uma revisão bibliográfica de artigos de periódicos, concluem que a preparação adequada dos profissionais (i.e: enfermeiros) é indispensável para alcançar sucesso no controlo da dor. Referem ainda que, o desempenho e o papel de enfermagem, como parte integrante de uma equipa multidisciplinar, na monitorização da dor (como 5º sinal vital), são fundamentais, pois pode comprometer todo o trabalho da equipa. Assim, torna-se importante, consciencializar estes profissionais, treinando-os para desempenhar este papel de forma eficaz (Fontes e Jaques, 2007).

Com a mesma preocupação e analisando os registos de enfermagem sobre dor e analgesia em doentes hospitalizados, Silva e Pimenta (2003), concluem que a adopção da avaliação diária e sistematizada (com base em instrumentos válidos) da dor do doente, contribuirá para o aperfeiçoamento da assistência em enfermagem.

No mesmo estudo de Silva e Pimenta (2003), foi elaborado um instrumento contendo parâmetros para a avaliação da dor que incluía a caracterização do local, da intensidade, da frequência, da duração e da qualidade da dor, devendo todos os parâmetros ser devidamente registados. Neste estudo, a coincidência entre o registo de enfermagem e o relato do doente foi pequena. Verificou-se que os registos eram pobres, embora, quando indagados, todos os doentes, tenham descrito o seu quadro algico quanto ao local, intensidade, duração, qualidade e prejuízos advindos da dor (Silva e Pimenta, 2003).

Na literatura, percebe-se uma elevada importância do relato verbal da dor para o seu controlo (Silva e Pimenta, 2003). Tendo como objectivo perceber a importância do relato verbal (dos doentes) na avaliação da dor, o estudo de 2004 de Frutuoso e Cruz, foca os desconfortos físicos e psicológicos causados pela mesma. Após a revisão da literatura, os investigadores salientam a importância do Questionário de McGill, que descreve aspectos qualitativos e quantitativos da percepção da dor. Este questionário foi adaptado e padronizado para a língua portuguesa por

Pimenta e Teixeira, em 1996, e contém uma larga quantidade de termos com a função de descrever aspectos quantitativos e qualitativos da dor. Contudo, quando lidamos com doentes com compromissos da consciência, com quadros de sedação ou grave compromisso da capacidade de comunicação verbal teremos que recorrer a outras estratégias, mantendo a perspectiva da dor como “5º sinal vital”.

Com o propósito de perceber a importância da aplicação dos instrumentos de avaliação da dor, em 2010 Bottega e Fontana desenvolveram um estudo intitulado: “A dor como quinto sinal vital - utilização da escala de avaliação por enfermeiros de um hospital geral”. Este estudo tinha como objectivo descrever as impressões dos enfermeiros acerca do uso de uma escala visual analógica, de avaliação da dor em adultos. Permitiu que os profissionais reconhecessem a dor como quinto sinal vital através da utilização da referida escala (Bottega e Fontana, 2010). Estes investigadores concluíram que a aplicação da escala para avaliação da dor é “uma maneira de melhor interpretar e entender a dor” (Bottega e Fontana, 2010, p.289), tornando-se a melhor forma de sistematizar o cuidado, facilitando a tomada de decisões, atendendo às necessidades do doente e permitindo acompanhar a eficiência do cuidado, humanizando-o.

Instrumentos padronizados têm sido elaborados, procurando facilitar a grande tarefa que é a avaliação da dor. Nos últimos tempos houve avanços significativos no que se refere à elaboração de instrumentos para mensuração da dor. Estes vieram possibilitar conhecer tanto a incidência, a duração e a intensidade da dor sentida, quanto o alívio obtido mediante aplicação de diferentes técnicas analgésicas (Batista *et al.*, 2008).

Da mesma opinião são os autores Batista, Cruz e Pimenta (2008), no estudo intitulado “Publicações sobre dor e diagnóstico de enfermagem em uma base de dados brasileira”, onde concluem que os resultados evidenciam que a dor - naturalmente subjectiva - apresenta a sua avaliação clínica dificultada. Assim, justificam a importância do desenvolvimento e utilização de instrumentos apropriados de avaliação da dor, que permitam colocar maior objectividade num fenómeno, como vimos, muito marcado pela subjectividade.

O estudo de Pedroso e Celich (2006), que se debruça sobre a “Dor: quinto sinal vital, um desafio para o cuidar em enfermagem” teve como objectivo identificar o conhecimento da equipa de enfermagem em relação à avaliação da dor, permitiu perceber que a grande maioria dos enfermeiros tem um conhecimento incipiente de escalas para avaliação da dor. Neste sentido e sendo a dor considerada um “sinal vital”, concluem e recomendam que a dor deve ser sempre avaliada em ambiente clínico, para se empreender um tratamento ou conduta terapêutica

adequada, acreditando que a eficácia do tratamento da dor e o seu seguimento dependem de uma avaliação e mensuração confiável e válida (Pedroso e Celich, 2006).

A questão que, assim, se levanta, olhando para a particularidade dos clientes com compromissos da consciência, quadros de sedação e / ou alteração da comunicação verbal, como aqueles que cuidamos diariamente, é: *Quais os instrumentos a que podemos recorrer, no sentido de aumentarmos a qualidade do processo de diagnóstico, avaliação e monitorização contínua das experiências dolorosas dos nossos doentes, no sentido de promover níveis de gestão e controlo da dor adequados?*

## 2. DEFINIÇÃO E DELIMITAÇÃO DA PERGUNTA

Antes de partir para a elaboração da pergunta de investigação é importante que o investigador se questione acerca do interesse, pertinência e da possibilidade de estudo; ou seja: se é exequível estudar aquilo a que o investigador se propõe.

A pergunta de investigação deve ser elaborada de forma a chegar a uma resposta sendo uma pergunta explícita respeitante a um tema de estudo que se deseja examinar, tendo em vista desenvolver conhecimento (Fortin, 2009).

Uma pergunta de investigação adequada é aquela à qual o investigador vai ser capaz de responder, através dos recursos que disponibiliza – viabilidade do estudo –, sendo que é importante ponderar conscientemente, se, de facto, se tratará de uma pergunta importante e com relevância. Assim, julgamos que a questão que elaborámos é altamente pertinente, é adequada à realidade onde exercemos funções e, de acordo com a metodologia que prevemos – revisão da literatura –, exequível.

Recorremos à metodologia PICO – Patient / Intervention / Comparing / Outcomes (Graig e Smyth, 2004) para delimitar a nossa pergunta de pesquisa. O quadro seguinte sintetiza os elementos da referida pergunta.

<b>P</b>	<b><i>Paciente / População</i></b>	<i>Doentes com alteração da consciência.</i>
<b>I</b>	<b><i>Intervenção</i></b>	<i>Avaliação da dor – através de escalas.</i>
<b>C</b>	<b><i>Comparação</i></b>	<i>Escalas disponíveis e adequadas à população.</i>
<b>O</b>	<b><i>“Outcomes” (resultados)</i></b>	<i>Viabilidade, validade e fidelidade das diferentes escalas.</i>

### Quadro I - PICO.

Assim como em qualquer outra abordagem de pesquisa, a definição da pergunta ou questão central de uma revisão sistemática da literatura é crucial (Sampaio e Mancini, 2007).

A revisão da literatura que projectámos pretende, no final, fazer emergir orientações para o processo de decisão, à escala do serviço onde exercemos funções, acerca das ferramentas e estratégias a mobilizar no sentido de promover cuidados de enfermagem progressivamente mais proficientes, no quadro da problemática da avaliação e controlo da dor. Apresentamos as perguntas de investigação e objectivo principal do estudo no Quadro II.



<b>Título</b>	Instrumentos de avaliação da dor em doentes com alteração da consciência: uma revisão sistemática.
<b>Perguntas</b>	Quais as escalas existentes para avaliar a dor em doentes com alteração da consciência? Que tipo de indicadores estas ferramentas incluem? Que tipo de propriedades psicométricas estas ferramentas possuem?
<b>Objectivo</b>	Analisar o potencial de utilização clínica das escalas disponíveis para efeitos de avaliação da dor, em doentes com alteração da consciência.

**Quadro II - Título, perguntas e objectivo do estudo.**

### 3. DEFINIÇÃO DOS CRITÉRIOS DE INCLUSÃO E EXCLUSÃO

Nesta fase interessa-nos clarificar os critérios de inclusão do material que nos permitiu levar por diante a revisão da literatura que empreendemos. O quadro III dá conta dos critérios de inclusão (e de exclusão) do material.

<b>Crítérios de selecção</b>	<b>Crítérios de Inclusão</b>	<b>Crítérios de Exclusão</b>
<b>Participantes</b>	Pessoas a partir de 18 anos. Doentes com alterações do estado de consciência.	Menos de 18 anos Pessoas que não tenham alteração do estado de consciência.
<b>Intervenções</b>	Avaliação da dor através de uma ferramenta / escala.	
<b>Desenho</b>	Estudos qualitativos e quantitativos (sem restrições). Publicados entre Jan. 2005 e Jun. 2011	

**Quadro III- Critérios de inclusão e exclusão do material.**

Para serem incluídos, os estudos teriam de cumprir os seguintes critérios: descrever uma escala de avaliação da dor para adultos com compromissos da comunicação, incapazes de relatar a sua experiência de dor; documento escrito em Inglês ou Português, disponível em texto integral e ser de acesso gratuito; data de publicação entre Janeiro de 2005 e Junho de 2011. Todos os estudos que não cumpriram cumulativamente estes critérios foram excluídos do estudo.

## 4. ESTRATÉGIA(S) DE “PROCURA” DO MATERIAL

Para realizar este tipo de pesquisa, os investigadores devem certificar-se de que todos os artigos importantes, ou possam ter algum impacto na realização da revisão, sejam incluídos. Seguindo este pressuposto, a procura da evidência deve ter início com a definição dos termos ou palavras-chave (descritores), seguida das estratégias de busca, definição das bases de dados e outras fontes de informação que se considerem relevantes (Sampaio e Mancini, 2007).

### 4.1. Pesquisa on-line e pesquisa local

A pesquisa electrónica (Quadro IV) e a pesquisa em repositórios locais (Quadro V) são intervenções importantes no processo de realização de uma revisão sistemática, considerando que sondagens eficientes maximizam a possibilidade de serem encontrados documentos importantes, num tempo reduzido (Sampaio e Mancini, 2007). Ambas as pesquisas foram realizadas no mês de Junho e apenas por um investigador.

Motores de busca	Bases de dados	Palavras utilizadas	Datas	Idiomas	Outros critérios definidos
EBSCO PUBMED	Academic Search Complete, CINAHL e Medline.	Pain, scale, nonverbal, adult, unconscious, behavioral, assessment, critical-care, observation, tool, intensive care, coma, impaired consciousness, measurement, brain-injured patients, nociception, sedated	01.2005 a 06.2011.	Português e Inglês	Pessoas com idade superior a 18 anos. <i>Links</i> com texto completo gratuito.

**Quadro IV-** Estratégia para selecção dos estudos e relatórios – *on-line*.

No quadro V fazemos a síntese da procura (local) realizada no âmbito das três instituições de ensino do Porto onde, mais frequentemente, os enfermeiros realizam formação pós – graduada. Assim, tínhamos a expectativa de poder encontrar, em particular, dissertações e teses que versassem a problemática em estudo.

<b>Repositórios</b>	<b>Palavras utilizadas</b>	<b>Datas</b>	<b>Idiomas</b>	<b>Outros critérios definidos</b>
Faculdade de Medicina da Universidade do Porto (FMUP), Escola Superior de Enfermagem do Porto (ESEP) e Instituto de Ciências Biomédicas Abel Salazar (ICBAS).	Dor	01.2005 a 06.2011.	Português e Inglês	Pessoas com idade superior a 18 anos. Apenas em humanos.

**Quadro V - Estratégia para selecção dos estudos – repositórios locais.**

## 5. TESTES DE RELEVÂNCIA

Os estudos de revisão sistemática da literatura preconizam que os artigos devem ser submetidos e seleccionados a partir de testes de relevância. Assim, neste capítulo são apresentados os testes de relevância efectuados (Pereira e Bachion, 2006).

### *5.1. Teste de relevância inicial*

O teste de relevância inicial é composto por uma lista de perguntas que geram respostas afirmativa ou negativas, cujas respostas são baseadas no título e/ou resumo (Quadro VI) (Pereira e Bachion, 2006).

<i>Perguntas</i>	<i>Número de documentos seleccionados</i>
Possui critérios para inclusão no estudo? Possui critérios para exclusão do estudo?	16 Documentos.

**Quadro VI-** Teste de relevância inicial.

Daqui resultou um conjunto de 16 documentos (artigos de revistas científicas e dissertações). Estes 16 documentos foram, após, submetidos a um teste de relevância de nível I.

### *5.2. Teste de relevância I*

O teste de relevância I permite refinar a selecção inicial, analisando os artigos na íntegra. Também composto por uma lista de perguntas claras que geram respostas afirmativa ou negativa e onde qualquer resposta negativa deve excluir o estudo em causa. (Quadro VII) (Pereira e Bachion, 2006).

<i>Perguntas</i>	<i>Número de documentos seleccionados</i>
<p>O estudo aborda o tema de interesse para a investigação?</p> <p>O estudo foi publicado no período seleccionado para a investigação proposta pelos pesquisadores do projecto de pesquisa de Revisão Sistemática?</p> <p>O estudo foi publicado no idioma seleccionado para a investigação pelos pesquisadores, e determinado no projecto de pesquisa de revisão sistemática?</p>	16 Documentos.

**Quadro VII- Teste de relevância I.**

### ***5.3. Teste de relevância II***

No teste de relevância II, as referências e resumos incluídos na amostra foram submetidos à avaliação apenas de um pesquisador. Seguindo o mesmo padrão dos testes de relevância anteriores, este teste é constituído por uma lista de perguntas claras, que geram respostas afirmativas ou negativas e onde qualquer resposta negativa deve excluir o estudo em causa (Quadro VIII) (Pereira e Bachion, 2006).

<i>Perguntas</i>	<i>Número de documentos seleccionados</i>
<p>Trata-se de um estudo que envolve directamente seres humanos como sujeitos?</p> <p>O estudo esta voltado para o problema específico que esta a ser investigado?</p>	16 Documentos.

**Quadro VIII - Teste de relevância II.**

Após, avançamos para o teste de relevância final.

### 5.4. Teste de relevância III (final)

Através da análise dos artigos na íntegra e com auxílio de um quadro sinóptico.

Este quadro sinóptico era constituído pelos seguintes itens de avaliação: autor(es), localização, ano, título, amostra (critérios de inclusão e exclusão), objectivos, intervenções, desenho de estudo, instrumentos de recolha de dados, limitações metodológicas, evidencia dos resultados e sua aplicabilidade, vantagens e desvantagens da utilização clínica e sugestões dos autores.

O teste de relevância final é realizado através de uma lista de perguntas claras, gerando respostas afirmativas ou negativa e onde qualquer resposta negativa deve excluir o estudo em causa (Quadro IX) (Pereira e Bachion, 2006).

<i>Perguntas</i>	<i>Número de documentos seleccionados</i>
<p>O tema objecto de investigação tem relação com o problema da prática clínica que se quer estudar?</p> <p>O objectivo do estudo tem relação com a questão que os avaliadores estão a estudar no momento?</p> <p>A metodologia do estudo utilizada está suficientemente descrita, de forma que outros pesquisadores possam realizar o mesmo estudo, de forma idêntica?</p> <p>Os resultados são compatíveis com a metodologia utilizada, merecendo credibilidade?</p> <p>A aplicabilidade dos resultados é possível na prática, sendo que os benefícios se mostram superiores aos riscos potenciais e justificam os custos?</p>	<p>9 Documentos. (Anexo I)</p>

#### Quadro IX - Teste de relevância final.

Depois de “questionarmos” os documentos ficamos com um conjunto de nove (9) documentos, os quais suportam a revisão realizada.

## 6. ESCOLHA DA REVISTA PARA APRESENTAÇÃO DO ARTIGO

Este capítulo foi elaborado com base na referência electrónica <http://www.esenfc.pt/rr/site/index.php?target=showContent&id=3623&menu=3671>, visitado no dia: 02 de Agosto de 2011.

A revista foi escolhida segundo os critérios pré-definidos pela Faculdade de Medicina da Universidade do Porto, que incluíam a escolha de uma revista indexada, portuguesa ou estrangeira.

A revista escolhida foi a *Revista Referência*, estando indexada nas bases de dados CUIDEN, CINAHL, Latindex e SciELO e integra preferencialmente artigos científicos resultantes de investigação empírica e, também, recensões teóricas, divulgação de programas e projectos, instrumentos técnico-metodológicos e reflexões críticas que se revelem de interesse pedagógico, científico e histórico para a enfermagem e para as ciências da saúde em geral.

A Revista apresenta, actualmente, as seguintes secções: Artigos de Investigação; Artigos de Revisão Sistemática; Artigos Teóricos (limite máximo de dois artigos por número); História e Memória; Unidade de Investigação. São publicados artigos de outro tipo, por exemplo recensões teóricas, biografias, etc., em números específicos.

### ***6.1. Normas de publicação de artigos científicos (segundo a revista Referência)***

A Revista de Enfermagem Referência cumpre os critérios de uma revista de divulgação internacional, indexada e divulgada em documento físico e em formato electrónico, em diversas bases de dados nacionais e internacionais. O interesse dos autores em submeterem artigos científicos de elevada qualidade prestigia a Revista, pelo que, damos a maior atenção aos processos de revisão, de forma a salvaguardar princípios científicos e éticos de edição e divulgação.



Os artigos submetidos para publicação na Revista de Enfermagem Referência devem obedecer aos seguintes critérios:

- Devem ser artigos científicos originais e versarem temas de saúde, enfermagem ou educação;
- O conteúdo dos artigos é da exclusiva responsabilidade dos seus autores, aos quais compete respeitar os princípios éticos da investigação e cumprir as normas e orientações de edição da Revista;
- Título: O artigo deverá incluir título informativo e sucinto (em português, inglês e espanhol; máximo de 16 palavras), sem abreviaturas, nem indicação da localização da investigação;
- Autores: Os autores devem ser em número não superior a 6, devidamente identificados, com o nome e respectivas habilitações, categoria profissional, instituição onde exercem funções, contactos (morada, e-mail, telefone) e fontes de financiamento do estudo (se for o caso);
- Resumo: O resumo do trabalho deve ser apresentado em português, inglês e espanhol, não deve exceder 200 palavras e deve incluir a descrição do contexto, objectivos, método, resultados e conclusões;
- Palavras-chave: O artigo deve apresentar, no máximo, 4 palavras-chave, transcritas de acordo com os descritores MeSH, em português, inglês e espanhol;
- Texto:
  - *Estrutura:* O Artigo científico deve ser estruturado em secções. Introdução, Quadro teórico, Metodologia, Resultados, Discussão, Conclusão;
  - *Formato:* O texto deve ser apresentado em formato Word, letra Arial, tamanho 11, espaço 1,5, páginas em formato A4, em coluna única, evitando negritos e sublinhados, variação de tipo de letra, fundos de cor, etc. Não deve incluir notas de rodapé. O artigo não deverá ultrapassar as 15 páginas incluindo referências, tabelas, quadros e figuras;
- Tabelas, quadros, gráficos e figuras: Devem ser incluídos(as), apenas, os(as) que sejam absolutamente necessários(as) para a compreensão do artigo e numerados(as) por ordem de inclusão no texto, em função de cada tipo. As tabelas e quadros devem apresentar o título em cabeçalho e os gráficos e figuras devem apresentar o título por baixo. Os

autores devem dar muita atenção à forma gráfica das tabelas e quadros, à clareza de apresentação dos dados e resultados e ao formato dos símbolos da linguagem estatística. No texto, os comentários aos dados e resultados devem anteceder as respectivas figuras, tabelas e gráficos.

- Citações: Todos os autores citados deverão constar da lista de referências bibliográficas. As *paráfrases* no texto devem indicar o autor e a data de edição. Exemplo: Pereira (2009) ou (Pereira, 2009). Deve indicar-se também o número de página, no caso de *citação textual*, tal como nos exemplos: Pereira (2009, p. 20) ou (Pereira, 2009, p. 20).
- Referências bibliográficas: As referências seleccionadas devem permitir colocar em evidência as publicações mais representativas do “estado da arte” da problemática (últimos 5 anos), resultando da pesquisa de bases de dados de revistas indexadas internacionais, incluindo a base de dados da Revista de Enfermagem Referência. As referências bibliográficas devem estar elaboradas de acordo com a Norma Portuguesa (NP 405). Todas elas deverão estar citadas no artigo. As fontes devem ser criteriosamente seleccionadas em função da sua pertinência e o corpo final não deve ultrapassar 20 referências, organizadas por apelido de autor (letra maiúscula) e ordenadas por ordem alfabética. O campo de data desloca-se para junto do último autor.

#### Procedimentos de submissão do artigo:

- Submissão electrónica: os artigos devem ser sempre submetidos electronicamente no site da Revista: <http://www.esenfc.pt/rr/site/>; para que possam submeter electronicamente os artigos, os autores deverão primeiro registar-se no referido site;
- Submissão por correio: Por correio dirigido ao Editor Chefe da Revista, para a Unidade de Investigação em Ciências da Saúde: Enfermagem, ESEnfC, deverão ser enviados os seguintes documentos:
  - Identificação dos autores (no máximo 6), com o nome e respectivas habilitações, categoria profissional, instituição onde exercem funções, contactos (morada, e-mail, telefone) e fontes de financiamento do estudo (se for o caso);
  - Artigo integral, sem elementos que façam referência aos autores;
  - Checklist de autoverificação, preenchida na totalidade;
  - Carta de declaração de originalidade;

- Termo de Transferência de Direitos de Autor, provando que concordam que o artigo, uma vez aceite, fique da propriedade da UICISA-E, não podendo, por isso, ser publicado noutra fonte.
- Processo de Revisão:
  - Os artigos propostos são apreciados num processo *Double blind* (duplamente cego, i.e., os intervenientes-autores, revisores, gestores de artigo, peritos de documentação e estatística -são anonimizados);
  - o artigo é enviado para 2 *Peer Reviewers* (Pares Revisores), os quais, o examinam e arbitram sobre a sua qualidade, dando as convenientes recomendações;
  - Neste processo, *Sempre que não se verifique acordo entre os dois revisores, o Editor Chefe indica um terceiro Revisor e consulta peritos de investigação*. A Direcção da Revista enviará ao autor informação sobre eventual aceitação definitiva, aceitação com alterações ou não aceitação. No caso de aceitação com alterações, os autores receberão os pareceres e recomendações sugeridas pelos *Peer Reviewers*,
  - O autor deve efectuar as alterações e reenviar o documento, via electrónica, no tempo regulamentado; o não cumprimento por parte dos autores do tempo indicado para proceder às alterações recomendadas pode ser motivo de exclusão do artigo do processo de revisão;
  - Cada artigo será, posteriormente, verificado por um “Gestor de artigo”, elemento do Conselho Editorial, que analisa a primeira versão do artigo e a versão corrigida, em função das recomendações dos *Peer Reviewers*;
  - O processo de revisão será efectuado *on-line*, o que permitirá aos autores, revisores e gestores de artigo receberem alertas automáticos;
  - As normas documentais relacionadas com a bibliografia e a linguagem dos descritores são verificadas por um especialista em Ciências Documentais; a linguagem estatística será verificada por professores especialistas; os resumos em inglês e espanhol serão verificados por especialistas de idioma;
- A decisão final acerca da oportunidade de publicação dos artigos é da responsabilidade do Editor Chefe da Revista.

O endereço da revista é: Revista "Referência", Unidade de Investigação em Ciências da Saúde: Domínio de Enfermagem, Escola Superior de Enfermagem de Coimbra, Av. Bissaya Barreto, apartado 55, 3001-091 Coimbra (Portugal).

## **7. INSTRUMENTOS DE AVALIAÇÃO DA DOR EM PESSOAS COM ALTERAÇÃO DA CONSCIÊNCIA: UMA REVISÃO SISTEMÁTICA**

Segundo as regras apresentadas pela revista Referência, deverão ser enviados os seguintes documentos: identificação dos autores, *checklist* de autoverificação, carta de declaração de originalidade e termo de transferência de direitos de autor (Anexo II) e o artigo integral (Anexo III).

## 8. CONCLUSÃO

A revisão sistemática da literatura é uma actividade fundamental para a prática baseada na evidência condensando uma grande quantidade de informação num único estudo (Pereira e Bachion, 2006).

Este tipo de documentos facilita o “acesso à informação, refinando os estudos e separando os de menor rigor académico dos fortemente confiáveis, além de servir de base científica para formulação de guias de condutas” (Pereira e Bachion, 2006).

Perante a necessidade de assegurar uma prática assistencial baseada em evidências científicas, as revisões sistemáticas da literatura surgem como uma “ferramenta ímpar no campo da saúde”, sintetizando as pesquisas disponíveis acerca de determinado assunto e, desta forma, direccionando a prática fundamentada em conhecimento científico (Sampaio e Macini, 2007).

A realização deste trabalho foi um desafio e integrou uma fase de aprendizagem no nosso percurso académico. Todavia, aquilo que emergiu do trabalho realizado, não temos dúvidas, será um importante contributo para a melhoria dos cuidados de enfermagem aos doentes internados no serviço onde exercemos funções...

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## **ANEXOS**



## **ANEXO I**

### **APRESENTAÇÃO DOS ARTIGOS SELECIONADOS**

## The Nociception Coma scale: A new tool to assess nociception in disorders of consciousness

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### ARTICLE INFO

#### Article history:

Received 3 May 2009

Received in revised form 12 August 2009

Accepted 23 September 2009

#### Keywords:

Nociception

Behavioral assessment

Brain injury

Consciousness

Vegetative state

Minimally conscious state

### ABSTRACT

Assessing behavioral responses to nociception is difficult in severely brain-injured patients recovering from coma. We here propose a new scale developed for assessing nociception in vegetative (VS) and minimally conscious (MCS) coma survivors, the Nociception Coma Scale (NCS), and explore its concurrent validity, inter-rater agreement and sensitivity. Concurrent validity was assessed by analyzing behavioral responses of 48 post-comatose patients to a noxious stimulation (pressure applied to the fingernail) (28 VS and 20 MCS; age range 20–82 years; 17 of traumatic etiology). Patients were assessed using the NCS and four other scales employed in non-communicative patients: the ‘Neonatal Infant Pain Scale’ (NIPS) and the ‘Faces, Legs, Activity, Cry, Consolability’ (FLACC) used in newborns; and the ‘Pain Assessment In Advanced Dementia Scale’ (PAINAD) and the ‘Checklist of Non-verbal Pain Indicators’ (CNPI) used in dementia. For the establishment of inter-rater agreement, fifteen patients were concurrently assessed by two examiners. Concurrent validity, assessed by Spearman rank order correlations between the NCS and the four other validated scales, was good. Cohen’s kappa analyses revealed a good to excellent inter-rater agreement for the NCS total and subscore measures, indicating that the scale yields reproducible findings across examiners. Finally, a significant difference between NCS total scores was observed as a function of diagnosis (i.e., VS or MCS). The NCS constitutes a sensitive clinical tool for assessing nociception in severely brain-injured patients. This scale constitutes the first step to a better management of patients recovering from coma.

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### 1. Introduction

Assessing nociception in severely brain-injured patients with disorders of consciousness represents a real challenge [20]. According to the International Association of Pain, “Pain is defined as an unpleasant sensory and emotional experience associated with real or potential tissue damage, or described in terms of such damage” [12]. Pain is hence a subjective first-person experience which has to be verbally or non-verbally reported to be accurately assessed. Nevertheless, self-reports are not possible to obtain in non-communicative patients, such as patients recovering from coma. For this reason, we will talk about nociception and not pain in this arti-

cle; nociception being defined as “an actually or potentially tissue damaging event transduced and encoded by nociceptors” [17].

Progress in intensive care has led to an increase in the number of patients who survive severe acute brain injury. These patients often pass through different altered states of consciousness before fully recovering awareness and, possibly, functional communication [18]. Patients in a vegetative state (VS) present no language production or comprehension [25] whereas patients in a minimally conscious state (MCS) may show reproducible but minimal and fluctuating signs of consciousness [7]. Neither VS nor MCS patients are able to reliably communicate a possible nociception by either verbal or non-verbal reports. At the same time, previous studies have shown that, contrary to VS patients [14], MCS patients may show a brain activation profile in response to noxious stimulation similar to healthy controls, suggesting a potential nociception [1,2] even if those cannot be expressed by the patient’s self-report.

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Hence, detecting behavioral signs of nociception in patients recovering from coma hence represents an important medical and ethical challenge.

Numerous standardized behavioral scales have been developed to help the detection of subtle signs of consciousness [15,18]. Up to now, however, no scale has been specifically developed to assess nociception in VS and MCS patients [20]. To date, the presence or absence of nociception is inferred via motor responses following noxious stimulation, such as stereotypical responses, flexion withdrawal and localization responses [20]. These responses are commonly respectively linked to brainstem, subcortical or cortical activity [22]. Localization to noxious stimulation is the only motor response considered as indicative of conscious perception [7]. Specifying the degree of nociception or its saliency to the person is not feasible by only considering these responses.

Several scales have been developed and validated to detect signs of nociception in non-communicative patients, such as in newborns [16,19] or in the demented elderly [5,27]. These scales are based on behavioral observations and often take into account facial expressions, verbalizations/vocalizations, body movements or changes in emotional status (e.g., cries) [11,24]. However, no scale has been specifically adapted for assessing nociception in patients recovering from coma.

In this context, the aim of this article is to explore concurrent validity, inter-rater agreement and sensitivity of a new scale that we developed for assessing nociception in severely brain-injured patients, the Nociception Coma Scale, with comparison to four other scales used for newborns or elderly.

## 2. Methods

### 2.1. Participants

This study is a prospective multi-centric study with patients recruited from the acute care, neurology, neurorehabilitation and nursing home centers which are part of the Belgian federal network for vegetative and minimally conscious states. Inclusion criteria were (1) age  $\geq 18$  years, (2) no administration of neuromuscular function blockers and no sedation within the 24 h of enrollment, (3) the presence of periods of eye opening (indicating preserved sleep-wake cycles), (4) a diagnosis of vegetative state (VS) or minimally conscious state (MCS), based on the behavioral assessment performed using the Coma Recovery Scale-Revised (see below) [6]. Exclusion criteria were (1) documented history of prior brain injury, (2) premorbid history of developmental, psychiatric or neurologic illness resulting in documented functional disability up to time of the injury, (3) superior limb contusions, fractures or paralysis. The study was approved by the Ethics Committee of the Faculty of Medicine of the University of Liège and written informed consent was obtained by the patients' legal representative.

### 2.2. Procedure

(1) Concurrent validity: Five behavioral scales were administered in randomized order by an experienced neuropsychologist (CS) to assess patients' responses to noxious stimulation: the Neonatal Infant Pain Scale (NIPS), the Faces, Legs, Activity, Cry, Consolability pain assessment tool (FLACC), the Pain Assessment In Advanced Dementia Scale (PAINAD), the Checklist of Non-verbal Pain Indicators (CNPI) and the Nociception Coma Scale (NCS). The NIPS assesses facial expression, arm and leg movements, crying, breathing pattern and state of arousal and is scored from 0 (no nociception) to 7 (severe nociception); a score superior to 3 is suggesting nociception [16]. The FLACC assesses face, legs and general body movements, crying and consolability and is scored from 0 to 10 (se-

vere nociception) [19]. The PAINAD assesses breathing, negative vocalization, facial expression, body movements and consolability and is scored from 0 (no nociception) to 10 [27]. The CNPI assesses verbal complaints, vocalizations, facial expression, agitation and localization to noxious stimulation and is scored from 0 to 6 – a score of 1–2 suggesting light nociception, 3–4 moderate nociception and 5–6 severe nociception [5]. The NCS was developed according to behaviors generally considered during assessment of non-communicative patients, such as facial expression, changes in mental status (i.e., cries), vocalizations/verbalizations or body movements [11,24]. In a pilot study, we also assessed breathing responses but later discarded this item because of the difficulty to assess this behavior in patients not benefiting from respiratory monitoring devices [4]. Previous studies have also shown that autonomic changes, such as respiration and heart rate are no reliable indicators of nociception [3,9]. Other behaviors linked to nociception, such as changes in interpersonal interaction (e.g., decreased social interactions) and changes in routine activities (e.g., appetite and sleep changes) are not assessed by the NCS. Indeed, the inclusion of these behaviors is not appropriate as patients recovering from coma have few interpersonal interaction and activities. Additionally, the assessment of these behaviors requires relatively long periods of observation and may be biased by other factors, such as anxiety or depression. The proposed NCS assesses motor, verbal, visual and facial responses. Its total score ranges from 0 to 12 (Table 1; [Complementary online material](#)).

In order to ensure a sufficient level of arousal, each behavioral scale was administered while patients showed spontaneous eye opening. Two noxious stimulations were administered before completing the behavioral scales. Upper extremities were extended (as far as possible for spastic patients) and noxious stimulation consisted of applying pressure on the fingernail bed [23] of the middle finger of the left and then of the right hand using a Newton-meter (Force Dial, FDN 200 model; Connecticut, USA; [www.wagnerinstruments.com](http://www.wagnerinstruments.com)). The Newton-meter allows the examiner to gauge the amount of pressure and hence allowed controlling the intensity of the noxious stimulation applied to the patient. Fingernail pressure was administered for a minimum of 5 s [6] and was stopped as soon as a behavioral response was observed. Behavioral responses were recorded for 10 s [6] after each noxious stimulus. Patients' consciousness level was assessed by using the Coma Recovery Scale-Revised (CRS-R) [6]. The CRS-R consists of 23 hierarchically arranged items that comprise six subscales addressing

**Table 1**

Protocol of the Nociception Coma Scale (detailed administration guidelines in [Complementary online material](#)).

<i>Motor response</i>
3 – Localization to noxious stimulation
2 – Flexion withdrawal
1 – Abnormal posturing
0 – None/flaccid
<i>Verbal response</i>
3 – Verbalisation (intelligible)
2 – Vocalisation
1 – Groaning
0 – None
<i>Visual response</i>
3 – Fixation
2 – Eyes movements
1 – Startle
0 – None
<i>Facial expression</i>
3 – Cry
2 – Grimace
1 – Oral reflexive movement/startle response
0 – None

arousal, auditory, visual, motor, oromotor/verbal and communication functions. The lowest item on each subscale represents reflexive activity while the highest item represents cognitively-mediated behaviors [6].

The concurrent validity was determined by comparing NCS total scores and subscores to the other scales (NIPS, FLACC, PAINAD and CNPI) by means of Spearman rank correlations.

(2) Inter-rater agreement: Fifteen patients (age range: 20–82 years; 8 females; 4 traumatic cases; 6 chronic cases) were assessed by two experienced neuropsychologists (CS and AV) during a single session in order to decrease the probability to observe inter-rater disagreement due to vigilance and/or consciousness fluctuations of the patient. Each examiner administered one of the two noxious stimulations.

To investigate the inter-rater agreement, Cohen's kappa ( $K$ ) tests determined the reproducibility of NCS total scores and subscores between the different raters.  $K$  values of 0.4 or less were considered poor, values between 0.4 and 0.6 were considered fair to moderate, values between 0.6 and 0.8 were considered as good inter-observer agreement and values greater than 0.8 suggested excellent agreements [13].

(3) Assessment of sensitivity: the capacity of the NCS and of the other four scales (i.e., the NIPS, the FLACC, the PAINAD and the CNPI) to differentiate between the behavioral pattern of each diagnostic category (i.e., VS vs. MCS) in response to noxious stimulation was assessed by performing a  $t$ -test on each scale's total scores as a function of the diagnosis.

### 3. Results

We included 48 patients of whom 28 were vegetative and 20 minimally conscious according to the behavioral assessment performed using the Coma Recovery Scale-Revised [6] (age range 20–82 years; 28 females). Etiology was traumatic ( $n = 17$ ), post-anoxic ( $n = 10$ ), encephalitis ( $n = 7$ ), ischemic stroke ( $n = 7$ ) and intracerebral hemorrhage ( $n = 7$ ). Thirty-one patients were assessed in the acute stage (i.e., <1 month post-injury) and 17 in the chronic stage (interval ranging from 1 month to 6 years). The amount of pressure that was applied (range 41–85 N/cm<sup>2</sup>) was not different according to the diagnosis (VS versus MCS) ( $t(46) = .53$ ;  $p = .60$ ). Time needed for NCS administrations varied between 1 and 5 min.

#### 3.1. Concurrent validity

Total NCS scores showed significant correlations with total scores of NIPS, FLACC, PAINAD and CNPI. Verbal, visual and facial expression subscores of the NCS also showed significant correlation with all four scales. The motor subscores were significantly correlated to the PAINAD (Table 2).

#### 3.2. Inter-rater agreement

Inter-rater agreement for the NCS total score was good ( $K = .61$ ). For the different subscales, mean kappa values were good to excel-

lent (i.e., motor ( $K = .93$ ), verbal ( $K = .93$ ), visual ( $K = .73$ ) and facial expression ( $K = .73$ ) subscales).

#### 3.3. Sensitivity

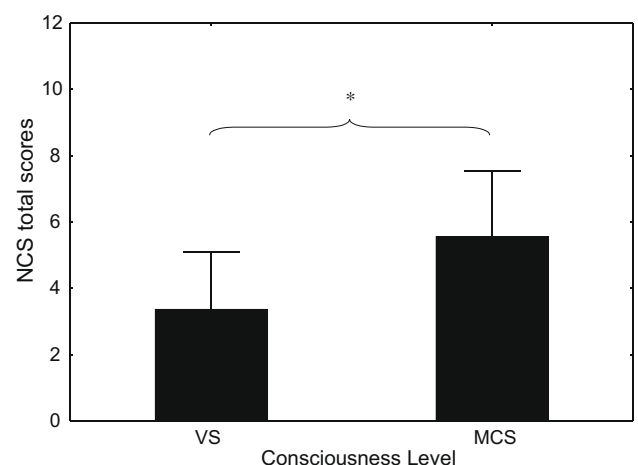
A significant difference ( $t(46) = 3.86$ ;  $p < .0005$ ) between NCS scores was obtained as a function of diagnosis (i.e., VS versus MCS). The NCS total score obtained in MCS patients ( $5.6 \pm 2.1$ ; range: 2–10) was higher than in VS patients ( $3.4 \pm 1.8$ ; range: 0–6) (Fig. 1). No differences according to level of consciousness were observed for the NIPS ( $t(46) = 1.36$ ;  $p = .18$ ), the FLACC ( $t(46) = 1.61$ ;  $p = .11$ ) or the PAINAD ( $t(46) = 1.86$ ;  $p = .07$ ) but the CNPI ( $t(46) = 2.61$ ;  $p = .01$ ) showed different total scores in VS ( $0.5 \pm 0.5$ ) as compared to MCS ( $1.1 \pm 0.9$ ).

In order to establish a relationship between NCS total scores and nociception intensity, we made additional analyses. Given that thresholds were previously determined for CNPI total scores [5], we performed an ANOVA on NCS total scores as a function of CNPI thresholds. Usually, a CNPI score of 0 suggests no nociception whereas a score of 1 or 2 suggests light nociception, a score of 3 or 4 moderate nociception and a score of 5 or 6 severe nociception. A significant difference was observed among NCS total scores according to CNPI thresholds, such as no nociception ( $2.5 \pm 1.5$ ), light nociception ( $5.1 \pm 1.7$ ) and moderate nociception ( $8.0 \pm 1.0$ ) (Fig. 2); severe nociception could not be assessed as none of the studied patients obtained a CNPI total score of 5 or 6.

Finally, no significant differences in NCS total scores were observed either as a function of the etiology ( $F = .29$ ;  $p = .98$ ) or the interval between assessment and brain insult (i.e., acute vs. chronic) ( $t(46) = .60$ ;  $p = .55$ ).

### 4. Discussion

The aim of this study was to investigate concurrent validity, inter-rater agreement and sensitivity of the Nociception Coma Scale, a new scale developed for assessing nociception in non-communicative patients recovering from coma (i.e., in VS and MCS patients). We obtained a good concurrent validity between the NCS and the four other validated scales suggesting that the NCS measures nociception similarly to the NIPS, the FLACC, the PAINAD and the CNPI. The highest correlation was observed between the NCS and the CNPI. All behaviors assessed by the CNPI (i.e., verbal complaints, vocalizations, facial expression, agitation and localization to noxious stimulation) are also assessed by the NCS. As regards NCS



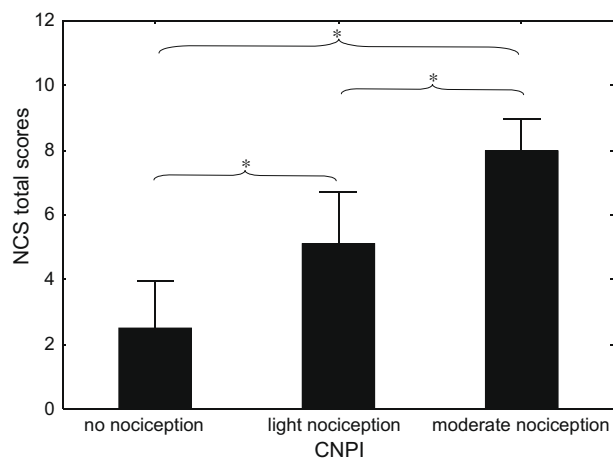
**Fig. 1.** Mean (and standard deviation) of NCS scores according to consciousness level (i.e., vegetative state – VS or minimally conscious state – MCS). Asterisk denotes a significant difference between consciousness level ( $p < .0005$ ).

**Table 2**

Correlation coefficients between NCS total (sub)scores and total scores in four other scales (i.e., the NIPS, the FLACC, the CNPI and the PAINAD).

NCS	NIPS	FLACC	CNPI	PAINAD
Total scores	.71*	.69*	.80*	.72*
Motor subscores	.26	.26	.25	.30*
Verbal subscores	.42*	.52*	.52*	.44*
Visual subscores	.49*	.30*	.56*	.36*
Facial expression subscores	.66*	.74*	.74*	.79*

\*  $P < .05$ .



**Fig. 2.** Mean (and standard deviation) of Nociception Coma Scale (NCS) scores according to the Checklist of Non-verbal Pain Indicators (CNPI) [5] thresholds (i.e., no nociception, light nociception and moderate nociception). Asterisk marks significant difference between thresholds ( $p < .05$ ).

subscores, verbal, visual and facial subscales were correlated to at least one scale suggesting that each of these NCS subscales assesses nociception. Inter-rater agreement for the NCS total score was good indicating that the scale yields reproducible findings across examiners. We also found good to excellent inter-rater agreement for each subscale. One could argue that the difference in the number of acute and chronic patients could bias our results. However, we did not find any difference in NCS total scores between acute and chronic patients suggesting that the time elapsed since the injury does not have an influence on the NCS total score. Concurrent validity and reliability was also comparable when analyzing given the 31 patients assessed in the acute stage (less than 1 month post-injury) and the 17 patients assessed in the chronic stage (with an interval ranging from one month to six years). Finally, NCS total scores were higher in MCS than in VS patients suggesting that our scale is adapted to assess nociception in patients with disorders of consciousness. Our results can be linked to previous functional neuroimaging studies showing a difference in brain activation between VS and MCS patients following noxious stimulation. Indeed, in VS patients, noxious stimulation only activates brainstem, thalamus and primary somatosensory cortex – the latter being functionally disconnected from the rest of the pain matrix encompassing secondary somatosensory, insular, anterior cingulate, parietal, premotor, and prefrontal cortices. The residual primary cortex activation in VS is therefore suggested to be isolated from higher-order associative cortical activity considered to be crucial in the conscious perception of the stimuli as well as from areas involved in the affective and cognitive processing of pain [14]. On the contrary, MCS patients were shown to have a brain activation following noxious stimulation very similar to that measured in healthy volunteers. The cortical integration observed in these patients is considered to possibly reflect nociception [2]. Moreover, MCS patients showed preserved activation of anterior cingulate cortex, suggesting preserved perception of stimulus unpleasantness [26]. It is therefore not surprising that the present behavioral study identified higher NCS total scores in MCS as compared to VS patients when Newton-meter intensity matched noxious stimuli were applied.

With the exception of the CNPI, the other scales, validated for newborns (i.e., the NIPS and the FLACC) or for people with dementia (i.e., the PAINAD and the CNPI) did not distinguish between VS and MCS patients suggesting that these scales are not adapted to assess nociception in patients with disorders of consciousness. Furthermore, as compared to the CNPI scores, the NCS scores, showed

wider ranges of subscores (e.g., a CNPI score of 0 corresponded to NCS scores between 0 and 5) suggesting that the NCS is more sensitive to detect different behavioral signs of nociception in VS and MCS. According to our results, the NCS represents a sensitive tool adapted for assessing nociception in severely brain-injured patients with disorders of consciousness.

Here, our objective was to develop a validated scale which could be used by clinicians even in case of short hospitalization periods and which could detect and monitor nociception in a standardized manner. An inadequate use of the NCS could be to use it in order to decide who is conscious or not and, therefore, who can receive treatment or not. First, the NCS is not a scale aiming to disentangle VS from MCS patients; others scales have been developed for this purpose [6]. Second, according to us and considering the levels of clinical uncertainty, pain treatment should be considered in all VS or MCS patients [20]. The real clinical interest of the NCS is to monitor patients in presence of a potential noxious stimulation (e.g., decubitus ulcers) and to give to the clinician a standardized but also adapted tool they can use for objectively detecting, communicating and following of non-communicative patient's behaviors and their daily management [4,20,21]. The use of the NCS will hence allow monitoring treatment in order to avoid sedative effects as well as under-uses of analgesics [21].

The NCS also offers a tool which, for research purposes, permits to better define behavioral signs of nociception and their correlation with functional neuroimaging data. Indeed, clinical signs (e.g., grimaces) are often considered as behavioral signs of nociception in the assessment of non-communicative patients [10,11,24]. However, these behaviors are not considered to be signs of consciousness as regards the diagnostic criteria of the VS published by the Multi-Society Task Force on PVS [25]. In fact, it has to be acknowledged that our current understanding of residual perception in VS and MCS is incomplete and awaits future studies employing standardized and validated clinical tools for the assessment of nociception confronted to functional fMRI [8].

In conclusion, the detection of nociception in VS and MCS patients remains challenging. Developing and validating a scale, such as the Nociception Coma Scale, constitutes the first step to a better management of patients recovering from coma. Further studies are needed to further investigate the validity of our scale in a larger pool of patients and additional functional neuroimaging studies will aim to identify the subcortical and cortical correlates of NCS assessment scores".

## Conflict of interest

The authors report no conflict of interest.

## Acknowledgments

This research was funded by the Belgian Fund for Scientific Research (FNRS), European Commission, James McDonnell Foundation, Mind Science Foundation, French Speaking Community Concerted Research Action (ARC-06/11-340), Fondation Médicale Reine Elisabeth, University of Liège and the CNRS/FNRS-CGRI collaboration funds.

## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.pain.2009.09.028.

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# RELIABILITY AND VALIDITY OF THE FACE, LEGS, ACTIVITY, CRY, CONSOLABILITY BEHAVIORAL TOOL IN ASSESSING ACUTE PAIN IN CRITICALLY ILL PATIENTS

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**CE** 1.0 Hour

## Notice to CE enrollees:

A closed-book, multiple-choice examination following this article tests your understanding of the following objectives:

1. Describe study findings related to the reliability and validity of the Face, Legs, Activity, Cry, Consolability (FLACC) Behavioral Scale in assessing pain in critically ill adults and children unable to self-report pain.
2. Describe 2 methods for reliable pain assessment of critically ill adults.
3. List 2 advantages that the FLACC tool may offer for observational pain assessment of critically ill adults.

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**Background** Few investigators have evaluated pain assessment tools in the critical care setting.

**Objective** To evaluate the reliability and validity of the Face, Legs, Activity, Cry, Consolability (FLACC) Behavioral Scale in assessing pain in critically ill adults and children unable to self-report pain.

**Methods** Three nurses simultaneously, but independently, observed and scored pain behaviors twice in 29 critically ill adults and 8 children: before administration of an analgesic or during a painful procedure, and 15 to 30 minutes after the administration or procedure. Two nurses used the FLACC scale, the third used either the Checklist of Nonverbal Pain Indicators (for adults) or the COMFORT scale (for children).

**Results** For 73 observations, FLACC scores correlated highly with the other 2 scores ( $\rho = 0.963$  and  $0.849$ , respectively), supporting criterion validity. Significant decreases in FLACC scores after analgesia (or at rest) supported construct validity of the tool (mean, 5.27; SD, 2.3 vs mean, 0.52; SD, 1.1;  $P < .001$ ). Exact agreement and  $\kappa$  statistics, as well as intraclass correlation coefficients (0.67-0.95), support excellent interrater reliability of the tool. Internal consistency was excellent; the Cronbach  $\alpha$  was 0.882 when all items were included.

**Conclusions** Although similar in content to other behavioral pain scales, the FLACC can be used across populations of patients and settings, and the scores are comparable to those of the commonly used 0-to-10 number rating scale. (*American Journal of Critical Care*. 2010;19:55-62)

Critically ill patients often cannot self-report their level of pain because of changes in cognition or physiological status or the presence of an endotracheal tube. Because of this inability, these patients have been excluded from clinical pain trials, leaving the patients vulnerable to the undertreatment of pain. In the absence of self-reports, behavioral observations have been used to detect and quantify pain in children, cognitively impaired patients, and adults.<sup>1-6</sup> However, testing of observation pain tools in adult critical care patients has been limited. Several simple tools, including the Face, Legs, Activity, Cry, Consolability (FLACC) Behavioral Scale (Table 1),<sup>4,7,8</sup> have been validated for use in acutely ill children, but limited data are available on pain assessment in critical care settings.<sup>9</sup> Identification and routine use of a simple yet valid and reliable observational tool to assess pain in these settings are necessary to ensure adequate pain management in critically ill patients.

Frequent and routine assessment of pain improves pain management for adults and children<sup>10</sup> and is considered essential for optimal care.<sup>11</sup> Additionally, clinical practice guidelines<sup>9</sup> for the use of sedatives and analgesics in critically ill patients highlight the importance of systematically and consistently assessing and documenting pain and response to therapy by using scales appropriate for the population of patients. These guidelines, as well

as previous reports,<sup>12,13</sup> suggest that pain assessment for patients who cannot communicate their pain should include subjective observation of pain-related behaviors (eg, movement, facial expression, posturing). Despite such recommendations and pain standards from the Joint Com-

mission, considerable gaps exist in pain assessment practices in critical care because of the limited research in this area.

Several investigators<sup>3,14-19</sup> have generated similar, qualitative descriptors of pain behaviors in adults and children with cognitive impairment and in critically ill adults and children. For instance, Mateo and Krenzischek<sup>17</sup> reported moderate correlations between

the degree of facial grimacing, muscle tension, and sounds documented by a nurse and the verbal description of pain reported by patients in the postanesthesia care unit. In another study, Puntillo et al<sup>18</sup> compared nurses' subjective ratings of pain, number of behavioral indicators (eg, movements, facial expression, posturing), physiological parameters, and patients' ratings in 31 critically ill surgical patients and found moderate correlations between nurses' ratings and number of behavior indicators, and between nurses' and patients' ratings.

Such data have led to the development of behavioral scales, including simple scales such as the Checklist of Nonverbal Pain Indicators (CNPI),<sup>1</sup> the Behavioral Pain Scale (BPS),<sup>20</sup> and the Critical-Care Pain Observation Tool (CPOT).<sup>21</sup> Almost all behavioral pain scales require some grading or scoring of facial expression, vocalizations, and bodily movements. The CNPI<sup>1</sup> requires simple scoring of each of 6 behaviors (vocalizations, grimaces, bracing, rubbing, restlessness, verbal complaint) as present or absent, to provide a total score of 0 to 6. The BPS<sup>20</sup> requires grading of 3 categories (facial expression, upper limb movement, and compliance with ventilation) to provide a score of 3 to 12. The CPOT<sup>21</sup> requires grading each of 4 behavioral categories (facial expression, body movements, muscle tension, and vocalization or compliance with ventilator) on a scale of 0 to 2 to provide a total score of 0 to 8. The COMFORT scale,<sup>22</sup> which has been widely studied in children, contains 8 categories (alertness, calmness, respiratory response, physical movement, muscle tone, facial tension, heart rate, and blood pressure); each category is scored from 1 to 5 to produce a total score of 8 to 40.

Each of these tools has good interrater agreement and good validity in differentiating nociceptive stimuli (eg, turning) from rest or pain-free situations.

Frequent pain  
assessment  
improves pain  
management.

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These studies indicate that observing behaviors and using simple scales can be effective in assessing pain in nonverbal patients.

To be clinically useful, pain assessment tools must be readily adaptable in busy settings such as the intensive care unit. Several characteristics affect the clinical usefulness of an assessment tool, including the tool's relative advantage compared with other tools, its compatibility (how similar the instrument is to other tools already used in the setting), and its complexity (ease of use).<sup>23,24</sup> Furthermore, the ability to use a single tool in different populations of patients may improve the clinical usefulness of the tool.<sup>25</sup>

Many observational pain scales lack these qualities. For instance, the most commonly used and recommended verbal self-report tool is the 0-to-10 number rating scale (NRS),<sup>9</sup> in which 0 indicates no pain and 10 indicates worst pain. Many observational tools, including those developed for critical care, have scales that differ from the 0-to-10 format, potentially confusing the clinical interpretation of pain scores. In contrast, with the FLACC tool, each of 5 behavioral categories, facial expression, leg movement, bodily activity, cry or verbalization, and consolability, is rated on a scale of 0 to 2 to provide an overall pain score ranging from 0 to 10, consistent with the NRS.

The FLACC Behavioral Scale includes behavioral categories and a variety of descriptors that are reliably associated with pain in children, adults with cognitive impairment, and critically ill adults, supporting the content validity of the tool in these populations. The FLACC tool is widely recognized and used in the United States and internationally and has been translated into several languages, including French, Chinese, Portuguese, Swedish, and Italian. Last, the tool in a revised form has a high degree of clinical usefulness in assessing pain in children with cognitive impairment, attesting to the tool's ease of use in the acute care setting.<sup>26</sup> These qualities may make the FLACC Behavioral Scale a useful instrument in critically ill adults.

We devised this prospective, observational study to evaluate the reliability and validity of the FLACC Behavioral Scale in assessing pain in critically ill adults and children who could not self-report pain.

## Methods

The study was approved by the institutional review board of the University of Michigan Health System, Ann Arbor, Michigan, which granted a waiver of consent. The study sample included patients, both

**Table 1**  
Face, Legs, Activity, Cry,  
Consolability (FLACC) Behavioral Scale<sup>a</sup>

Item	Score		
	0	1	2
Face	No particular expression or smile	Occasional grimace, frown, withdrawn or disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless, or tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, or tense	Arched, rigid, or jerking
Cry	No cry	Moans, whimpers, or occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to; distractible	Difficult to console or comfort

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adults and children, who were present in any of the critical care units in the medical center during the study period (2002-2004). Patients were included if they could not self-report their pain (eg, because of intubation with or without change in cognition), and if they had an underlying condition associated with pain or were undergoing a procedure known to cause pain. Patients receiving muscle relaxants were excluded.

## Data Collection

Observations were made by 3 intensive care unit nurses during the routine care of each patient as follows: Before administration of an analgesic, or during a painful procedure such as turning or suctioning, nurses observed the patient and simultaneously, but independently, scored pain behaviors during a 1- to 2-minute period. Nurses had no knowledge of the scores of their fellow nurses. Two of the nurses used the FLACC tool to score pain behaviors; the third nurse used the CNPI for adults and the COMFORT Scale for children.<sup>22</sup> Each patient was observed again by the same nurses approximately 15 to 30 minutes after the first observation. Patients' demographics, illness, type of procedure, and analgesic administered were recorded.

**Observation of behaviors can be effective in assessing pain in nonverbal patients.**

**Table 2**  
Description of the sample<sup>a</sup>

Characteristic	Adults (n = 29)	Children (n = 8)
Age, y		
Mean (SD)	51 (38)	5.6 (5.6)
Range	24 - 70	0.13 - 13
Sex <sup>b</sup>		
Male	17 (59)	4 (50)
Female	12 (41)	3 (38)
Race		
White	23 (79)	8 (100)
African American	3 (10)	0
Other	3 (10)	0
Diagnosis		
Medical	19 (66)	1 (12)
Neurological-medical	6 (21)	0
Neurosurgical	2 (7)	0
Surgical	2 (7)	7 (88)
Treated with mechanical ventilation	23 (79)	3 (38)
Cognitive impairment	16 (55)	1 (12)
Acute delirium	11 (38)	Not applicable

<sup>a</sup> Values are number (%) unless indicated otherwise. Because of rounding, not all percentages total 100.

<sup>b</sup> Data on sex missing for 1 child.

### Data Analyses

SPSS software (SPSS Inc, Chicago, Illinois) was used to analyze the data. Total FLACC and CNPI scores were treated as ordinal data, and each category within the FLACC was treated as ordinal, polychotomous data, as recommended and used by previous investigators.<sup>27-29</sup> Interrater reliability was evaluated by using intraclass correlation coefficients, which determine the strength of association and measure of chance-corrected agreement. Additionally, exact agreement for scores

within each of the 5 FLACC categories was evaluated by using  $\kappa$  statistics. In accordance with well-established criteria,<sup>30</sup> interrater agreement for total FLACC scores was considered excellent at an intraclass correlation coefficient of 0.75.

Because each FLACC category contains only 3 items, generating comparatively less variance and thereby limiting the magnitude of correlations,<sup>31</sup> an intraclass correlation coefficient of 0.41 was accepted as adequate agreement, and a coefficient of 0.6 was considered good to excellent agreement.<sup>32</sup>

Criterion validity was evaluated by using correlation coefficients to compare FLACC scores with CNPI scores. Correlation coefficients greater than 0.75 were considered indicative of excellent relationships. The construct validity of the FLACC tool was evaluated by using Wilcoxon signed rank tests

for paired data to compare scores before and after analgesic administration or during and after a painful procedure. *P* values less than .05 were accepted as significant. The internal consistency of reliability of the items in the FLACC tool was measured by using Cronbach (coefficient)  $\alpha$  values. Cronbach  $\alpha$  values of 0.7 or greater were considered indicative of excellent internal consistency. A principal component and exploratory factor analysis were performed to identify underlying factors that explained the variance in the FLACC total scores; loading factors of 0.45 or greater were considered acceptable.

### Sample Size

The sample size was conservatively based on a moderate reliability correlation coefficient between FLACC scores. For  $\alpha = 0.05$  and  $\beta = 0.1$ , a total of 25 observations would be needed to reveal a modest correlation of at least 0.6.<sup>33</sup> A minimum of 65 observations with at least 13 paired observations (eg, before and after analgesia) would be needed to ensure a sufficient number of FLACC scores across the spectrum (ie, mild, moderate, and severe pain scores). This sample size would be sufficiently large to satisfy the stronger correlations required for criterion validity (ie,  $r = 0.75$ ) and to establish a minimum decrease in pain scores from a mean of 5.3 (SD, 2.8) to a mean of 2 (SD, 2.4).

### Results

A total of 73 observations were obtained in 29 critically ill adults and 8 children. Table 2 gives a description of the patients.

#### Criterion Validity

FLACC scores correlated significantly with CNPI scores, supporting excellent criterion validity in adults ( $\rho = 0.963$ ;  $P < .01$ ). Additionally, FLACC and COMFORT scores were highly correlated ( $\rho = 0.849$ ;  $P < .01$ ), supporting criterion validity in critically ill children.

#### Construct Validity

FLACC pain scores decreased significantly after administration of an analgesic or from painful to nonpainful situations (mean, 5.27; SD, 2.3 vs mean, 0.52; SD, 1.1;  $P < .001$ ), supporting excellent construct validity across populations of patients.

#### Reliability

Agreement was excellent between observers for each category of the FLACC, as well as for total FLACC scores, supporting the interrater reliability of the tool

**FLACC scores showed excellent criterion validity in adults.**

**Table 3**  
Measures of interrater reliability between scores on the Face, Legs, Activity, Cry, Consolability Behavioral Scale<sup>a</sup>

Item	Total observations (n = 73)	Adults (n = 60)	Children (n = 13)	Treated with mechanical ventilation (n = 34)
Face	0.90 [0.83-0.94] 80% (0.68)	0.93 [0.88-0.96] 84% (0.76)	0.74 [0.10 -0.93] 58% (0.33)	0.90 [0.80-0.95] 76% (0.64)
Legs	0.956 [0.93-0.98] 89% (0.82)	0.97 [0.94-0.98] 91% (0.85)	0.92 [0.73-0.98] 83% (0.71)	0.94 [0.88-0.97] 79% (0.74)
Activity	0.91 [0.85-0.95] 82% (0.70)	0.93 [0.87-0.96] 91% (0.74)	0.76 [0.17-0.93] 75% (NA) <sup>b</sup>	0.95 [0.89-0.97] 85% (0.76)
Cry	0.67 [0.44-0.81] 89% (0.69)	0.72 [0.53-0.86] 93% (NA) <sup>b</sup>	0.43 [-0.97 to 0.84] 75% (NA) <sup>b</sup>	0.60 [0.20-0.80] 91% (0.72)
Consolability	0.95 [0.91-0.97] 86% (0.78)	0.96 [0.93-0.98] 89% (0.82)	0.87 [0.56-0.96] 75% (0.60)	0.96 [0.93-0.98] 88% (0.81)
<b>Total score</b>	0.96 [0.93-0.97]	0.98 [0.97-0.99]	0.85 [0.52-0.96]	0.96 [0.92-0.98]

Abbreviation: NA, not applicable.

<sup>a</sup>Data are intraclass correlation coefficient [confidence interval]; % exact agreement ( $\kappa$ ), where applicable.

<sup>b</sup>Unable to calculate  $\kappa$  values in unequal contingency tables.

in assessing pain in critically ill patients (Table 3). Agreement was also adequate to excellent when data on adults, children, and patients receiving mechanical ventilation were analyzed separately (Table 3).

### Internal Consistency and Factor Analysis

Internal consistency of the FLACC was excellent, as indicated by Cronbach  $\alpha = 0.882$ , when all items were included. Each category correlated highly with the others (Spearman  $\rho = 0.69$ -0.92;  $P < .001$ ) except for the cry category ( $\rho = 0.18$ -0.36). Additionally, the Cronbach  $\alpha$  improved to 0.934 when the cry category was removed, but decreased slightly with removal of other items. In the exploratory factor analysis, 1 component accounted for 68.9% of the variance in FLACC scores; 4 items contributed to this component: face (0.86), legs (0.94), activity (0.90), and consolability (0.95). These findings indicate that 4 categories of the FLACC reflected the pain expression factor in this sample of patients.

### Discussion

Use of behavioral pain tools may help in assessing pain in critical care patients, but the tools must have good reliability and validity and be clinically feasible.<sup>13</sup> Clinical feasibility, or the ability to readily adapt an instrument for routine assessment and documentation, may depend on a tool's simplicity and its compatibility with other tools used in the clinical setting,<sup>23</sup> as well as on the ability to use the tool across settings or populations of patients.<sup>25</sup> We evaluated the well-known FLACC behavioral pain tool and showed that the tool has excellent

interrater reliability, criterion validity, and construct validity, thereby supporting its usefulness in assessing pain in critical care patients.

Indisputably, self-report remains the gold standard for pain assessment, yet many patients cannot report their pain, an inability that may make them vulnerable to poor pain management. Many tools have been developed to aid in assessing pain for patients who cannot self-report; however, few of the tools have been tested in critically ill patients who cannot self-report. We found that the FLACC Behavioral Scale has excellent psychometric properties, including reliability, criterion validity, and construct validity, in assessing pain in these patients. Interestingly, 4 categories (face, legs, activity, and consolability) were predictive of most of the variance (68.5%) in scores. The cry category correlated poorly with other categories and slightly lowered the internal consistency of the tool. These findings are not surprising; many of the patients in our study were nonverbal and many had endotracheal tubes.

The COMFORT Scale, BPS, and CPOT, which were all developed for scoring pain in the intensive care unit, include a category for assessing respiratory response or compliance with ventilation, a category that may be useful for assessing pain in patients receiving mechanical ventilation.<sup>20-22</sup> In a sample of sedated adults receiving mechanical ventilation,<sup>20</sup> compliance with mechanical ventilation had a smaller,

**Pain scales that include compliance with ventilation may be useful in ventilated patients.**

Behavioral pain tools assess the patient's expressions of distress and discomfort.

but significant, coefficient in accounting for variance in pain expressions, supporting the inclusion of compliance descriptors in tools used to assess pain in patients receiving mechanical ventilation. However, a recent study<sup>34</sup> validating use of the BPS in sedated patients suggested that newer modes of ven-

tilation that allow for variation in patients' needs may reduce the reliability of this category in assessing discomfort. Interestingly, in our study, the FLACC had good reliability in assessing pain even in the subset of patients receiving mechanical ventilation. However, the addition of descriptors (eg, breath holding, splinting, blocking ventilation) in

the cry category that allow for scoring pain in patients who are intubated and receiving mechanical ventilation may enhance pain assessment in these patients. Indeed, similar minor revisions related to respiratory patterns, in addition to other revisions, improved the reliability of the FLACC tool in assessing pain in cognitively impaired children.<sup>16</sup>

Several guidelines<sup>9,12,13</sup> suggest that in addition to observation of behaviors, pain assessment in the critically ill should include consideration of physiological measures such as heart rate, blood pressure, and respiratory rate. Importantly, changes in these measures are nonspecific to pain and may indicate other pathological changes.<sup>12,13</sup> In a recent study<sup>35</sup> of the COMFORT scale in the pediatric intensive care unit, 97% of the variance in pain scores was explained by 6 behavioral categories, including a category for scoring respiratory or compliance behaviors, but not by heart rate or blood pressure. These findings led the authors<sup>35</sup> to conclude that these parameters should be removed from the COMFORT scale.

The fact that behavioral pain tools provide a score of a patient's expressions of distress and discomfort must be emphasized. In addition to pain, these behaviors have many potential underlying sources, including physiological abnormalities (eg, cardiorespiratory compromise) and anxiety. Such conditions are com-

mon in critically ill patients, and therefore a patient's medical condition and current circumstances, including response to analgesia, must be considered when behavioral pain scores are interpreted.

Additionally, most behavioral pain tools, including the FLACC, COMFORT, BPS, and CPOT, were developed to score intensity of acute pain. It has

been suggested that behavioral distress related to pain lessens over time, despite persistence of pain.<sup>36</sup> Withdrawn or disinterested expressions and immobility may replace behaviors such as grimacing, vocalizations, and movements. The variety of descriptors included in the FLACC tool were meant to indicate some of the differences observed from patient to patient. However, assessment of chronic or long-term pain should include other observations such as activity, quality of sleep, and expressions of depression.

The ability to generalize our findings may be limited by the following design issues. First, the same nurses scored pain before and after administration of analgesics, a practice that could have resulted in a reporting bias. However, in previous studies<sup>5,16</sup> in which nurses were blinded to treatment, similar changes in FLACC scores occurred, providing some external validity to our data. Second, we included a variety of medical and surgical patients in the sample to indicate usefulness across critical care settings. However, because of the small sample size, we could not analyze data separately for each group. Further study in these subsets of patients may provide greater insight into behavioral changes that best describe pain in these groups.

## Conclusion

The FLACC behavioral pain tool has excellent reliability and validity in assessing pain in critically ill adults and children. Although similar in content to other observational pain scales, the FLACC tool may offer an advantage: it can be used across populations and settings, and FLACC scores are comparable to scores generated by using 0-to-10 number rating scales.

## ACKNOWLEDGMENTS

This study was conducted at the University of Michigan Health System in Ann Arbor.

## FINANCIAL DISCLOSURES

None reported.

## eLetters

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Behavioral pain scores must be interpreted in light of the patient's medical condition, including response to analgesia.



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**CE Test** Test ID A1019013: Reliability and Validity of the Face, Legs, Activity, Cry, Consolability Behavioral Tool in Assessing Acute Pain in Critically Ill Patients . *Learning objectives:* 1. Describe study findings related to the reliability and validity of the Face, Legs, Activity, Cry, Consolability (FLACC) Behavioral Scale in assessing pain in critically ill adults and children unable to self-report pain. 2. Describe 2 methods for reliable pain assessment of critically ill adults. 3. List 2 advantages that the FLACC tool may offer for observational pain assessment of critically ill adults.

**1. Which of the following patient types have been studied previously for validation of the Face, Legs, Activity, Cry, Consolability (FLACC) Behavioral Scale?**

- a. Acutely ill children
- b. Adults with dementia and cognitive impairment
- c. Critically ill adults and children
- d. Adults with expressive aphasia

**2. Which of the following is *most* likely to cause a critically ill patient to be unable to self-report his or her level of pain?**

- a. Inability to communicate
- b. Presence of an endotracheal tube
- c. Inadequate nutrition
- d. Sleep deprivation

**3. Which of the following is cited by the authors to explain why gaps exist in pain assessment practices in critical care?**

- a. Recommendations of the Joint Commission are not followed.
- b. Pain assessment is difficult when the patient is sedated.
- c. Limited research has been done on pain assessment practices in critical care.
- d. Multiple scales for pain assessment are available to critical care nurses.

**4. Which of the following are requirements common to almost all behavioral pain scales?**

- a. Some grading or scoring of respiratory rate, heart rate, and blood pressure
- b. Some grading or scoring of facial expressions, vocalizations, and body movements
- c. Some grading or scoring of cognition, level of consciousness, and attention span
- d. Some grading or scoring of response to painful stimulation by posturing or withdrawal

**5. Which of the following are the categories for assessment in the FLACC pain tool?**

- a. Face, activity, compliance with the ventilator, cry
- b. Face, limbs, activity, sounds, calmness
- c. Face, legs, physical movement, cry, calmness
- d. Face, legs, body activity, cry, consolability

**6. Which of the following characteristic may affect the clinical usefulness of a pain assessment tool?**

- a. Complexity (ease of use)
- b. Unique (uses different factors for evaluation)
- c. Electronic (computerized documentation)
- d. Reading level (6th grade)

**7. How is pain assessed with the Number Rating Scale?**

- a. Verbal self-report using common descriptive terms for pain
- b. Five behavioral categories that are each rated on a scale of 0 to 2
- c. Verbal self-report where 0 indicates no pain and 10 indicates worst pain
- d. Pain is reported by the nurse on a scale of 0 to 10 based on patient assessment findings

**8. Which of the following patient types were excluded from the study?**

- a. Intubated patients
- b. Patients undergoing a procedure known to cause pain
- c. Patients who could not self-report pain
- d. Patients receiving muscle relaxants

**9. What is considered the “gold standard” for pain assessment?**

- a. Self-report
- b. Use of a behavioral pain assessment tool
- c. Wong-Baker faces
- d. Use of the Numeric Rating Scale

**10. Which of the following behavioral observations would result in a FLACC score of 0?**

- a. No expression, relaxed position, lying quietly, no cry, and appears content
- b. Grimace, restless, moves easily, no cry, and can be distracted
- c. Clenched jaw, kicking, rigid movement, moans, and can be reassured
- d. No expression, restless, moves easily, no cry, and can be reassured

**11. What conclusion did the investigators reach related to the use of the FLACC behavioral scale in assessing pain?**

- a. The FLACC tool has validity in assessing pain in specific populations.
- b. The FLACC tool has poor reliability and validity in assessing pain in critically ill adults.
- c. The FLACC tool had excellent reliability and validity in assessing pain in critically ill adults.
- d. The FLACC tool has poor correlation to scores generated by using 0 to 10 number rating scales.

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## **O FENÓMENO DA DOR NUMA UNIDADE DE CUIDADOS INTENSIVOS**

**Fonte:** Marques, Fátima - O fenómeno da dor numa Unidade de Cuidados Intensivos. Dissertação Mestrado em Psicologia da Dor apresentada ao Instituto Superior de Ciências da Saúde do Norte. 2009.

### **Resumo**

O estudo de investigação apresentado nesta dissertação insere-se no domínio do fenómeno da dor no âmbito dos cuidados intensivos (CI), mais especificamente, na problemática da avaliação da dor no doente sedado e/ou ventilado, por isso, impossibilitado de a expressar verbalmente. Porque ainda são escassos os estudos a nível nacional sobre este tema, decidimos realizar um estudo de cariz descritivo, exploratório e de validação de instrumentos de avaliação da dor.

Temos como principal finalidade, através da certificação da validação de instrumentos de avaliação da dor, dar um contributo no processo de avaliação e consequente diagnóstico e tratamento da dor, no contexto dos CI. Com este contributo esperamos poder perspectivar, num futuro próximo, uma melhor qualidade dos cuidados de enfermagem, que certamente se repercutirá numa melhor qualidade de vida do doente.

Estruturalmente o estudo encontra-se dividido em duas partes. A primeira parte diz respeito ao enquadramento teórico, onde são abordados aspectos relevantes na abordagem do tema: "O fenómeno da dor numa unidade de cuidados intensivos". A segunda parte corresponde ao estudo de investigação propriamente dito, ou seja, aos nossos contributos para o estudo do fenómeno da dor numa UCI. Esta segunda parte do estudo encontra-se estruturada em três fases, correspondentes aos objectivos gerais definidos.

Na primeira fase do estudo, de carácter qualitativo, avaliamos a perspectiva de 18 enfermeiros sobre a problemática da dor no contexto dos CI. Conclui-se que a dor é um fenómeno complexo, frequente e relevante, que se manifesta essencialmente por indicadores fisiológicos e comportamentais, e finalmente, que seria importante a utilização sistemática de instrumentos de avaliação da dor na prática diária dos cuidados, devido às inúmeras vantagens que lhes são inerentes.



Na segunda fase realizou-se o processo de tradução, validação e adaptação cultural de dois instrumentos de avaliação da dor, para estes doentes específicos, ao qual estão inerentes, basicamente, métodos de investigação quantitativa. Para este processo de validação recorreu-se à análise estatística quantitativa das características psicométricas dos instrumentos usados na avaliação de 94 doentes, que revelou, de forma similar, índices de validade, fidelidade e sensibilidade capazes de lhes conferir credibilidade na sua utilização.

Na terceira fase, e tendo por base os dados recolhidos durante a fase anterior, desenvolvemos um estudo epidemiológico, de cariz quantitativo, sobre a incidência, variabilidade e intensidade da dor, na realidade nos doentes que fizeram parte da amostra. Conclui-se que os doentes durante a realização de procedimentos nociceptivos expressam dor, estando o seu aparecimento e a sua intensidade correlacionada com determinados factores, como o nível de sedação e os procedimentos realizados.

Com este estudo esperamos reunir um conjunto de dados de interesse que permitam aos profissionais de saúde, nomeadamente aos enfermeiros, refletirem sobre a problemática da dor e essencialmente despertar para a importância da utilização de instrumentos de avaliação da dor, que são uma clara mais valia para a qualidade do “CUIDAR” e consequente QUALIDADE DE VIDA DA PESSOA.



# Further Validation of the Nonverbal Pain Scale in Intensive Care Patients

Anne Marie Kabes, RN, BSN, CCRN  
Janet K. Graves, RN, PhD  
Joan Norris, RN, PhD

## PRIME POINTS

- Pain assessment is difficult but vital for sedated patients receiving mechanical ventilation in ICUs.
- Few nonverbal scales have been developed for assessing pain, and few studies of their validity and reliability have been published.
- The authors compare the original and revised versions of the Nonverbal Pain Scale in sedated patients receiving mechanical ventilation in an ICU and present the results.

Pain assessment and management are components of the Joint Commission 2001 standards of care that require every patient to be assessed for pain. Assessment and management of pain are essential to provision of quality care in all settings. Several valid and useful scales for rating the intensity of pain in most children and adults are available. These various verbal (no pain to worst pain), pictorial (Faces scale), and numeric (1-10) scales for rating pain are commonly used with alert adult or child patients in hospitals and home care. These scales require patients to be able to cognitively indicate a position on a line from no pain to worst possible pain, select a picture that expresses their pain level, or select a number between 1 and 10 to represent their pain level. It is important to differentiate between pain intensity ratings based on patients' self-reports of pain severity and pain behavior scales that list a number of observable characteristics that can only indicate the presence or apparent absence of pain in patients who cannot self-report.

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Observational rating scales, such as the Faces, Legs, Activity, Cry, and Consolability scale (FLACC), for infants and preverbal children are also commonly used. Recently, interest has increased in the development and validation of observational pain scales for use in cognitively impaired patients and critically ill patients who are sedated and receiving mechanical ventilation in intensive care units (ICUs). A group of Canadian nurse investigators<sup>1</sup> described observable physiological and behavioral indicators of pain in critical care patients receiving mechanical ventilation and noted that pain documentation was incomplete or inadequate, adding that lack of a pain assessment tool was most likely a contributing factor. Observational indicators of behaviors associated with pain can vary by patient populations. Pasero and McCaffery<sup>2</sup> described how ratings based on ventilator compliance should not be appropriate in patients who are not receiving mechanical ventilation and pointed out that heavily sedated patients may have severe pain but be unable to move. Such patients will have low scores on observational ratings that use

ventilator compliance or leg or arm movements as indicators.<sup>2</sup> For ICU patients who cannot self-report, observational behavioral rating scales have been developed for rating pain. Only limited reports of the validity and reliability of those scales have been published.

In a search for an acceptable pain assessment tool for these patients, staff at Creighton University Medical Center Hospital initially tried the FLACC<sup>3</sup> behavioral pain scale in the ICU. The FLACC scale was designed to rate indicators of pain in infants and preschool children and is used extensively for that purpose. Wegman<sup>4</sup> noted that the FLACC scale has also been used in adult patients as an observational pain scale, primarily because of the Joint Commission requirement for pain assessment of all patients and the difficulty in finding valid and reliable nonverbal pain scales appropriate for adults who have cognitive impairments or are sedated and receiving mechanical ventilation. The ICU nurses considered the FLACC scale unsatisfactory for critically ill adult patients because it includes crying behaviors and reactions to comforting methods, which vary greatly in adults. Thus, the nurses did not use the FLACC consistently.

A subsequent review of the literature located 2 scales designed for use in adult patients in the ICU who are sedated, comatose, and/or receiving mechanical ventilation; the Behavioral Pain Scale (BPS)<sup>5</sup> and the Nonverbal Pain Scale (NVPS).<sup>6</sup> These scales were of particular interest because they addressed these particular ICU problems. The hospital research council reviewed the literature on both scales and selected the NVPS for further testing in the ICU. This selection was based on the preference of these clinicians for a tool that included physiological indicators. The BPS focuses on behavioral observations only (facial expression, cry, and movements), whereas the NVPS includes behavioral and physiological indicators. Although the ICU nurses recognized that physiological indicators should not be used as the sole indicators of pain level, they thought that a combination of behavioral and physiological indicators of pain would be more comprehensive<sup>7,8</sup> than use of behavioral indicators alone. Additionally, they thought that use of the BPS might be confusing because the maximum score is 8 and that might be seen as lesser pain when compared with the maximum score of 10 used in other pain scales.

Two versions of the NVPS have been described.<sup>4,6</sup> The original NVPS rated facial expression, activity, guarding, change in vital signs (physiologic I), and other physiologic signs (physiologic II; see rating levels for each item in Table 1).

Odhner et al<sup>6</sup> reported an acceptable level of internal consistency ( $\alpha=0.74$ ) and interrater reliability (0.78) for this initial version, but noted that the physiologic II category discriminated less well than did the other subscales.

Wegman<sup>4</sup> reported a revision in the NVPS in which a respiratory category was substituted for the former physiologic II category. The new respiratory category included ratings of baseline respiratory rate, oxygen saturation as measured by pulse oximetry, and compliance with the ventilator (see Table 1, item 5A for rating levels). This revision was described in a presentation and a letter to the editor,<sup>4</sup> but no further testing was reported.

Because the original NVPS had been validated only once by the authors,<sup>6</sup> and the validation of the revised version had not been published, the research council made a decision to test both the initial and revised items of the NVPS to compare the validity and reliability of the 2 versions. The purpose of this study was to further validate a nonverbal pain scale for ICU patients who are sedated, receiving mechanical ventilation, or otherwise unable to express their pain. The research question was as follows: Which version of the NVPS is the most valid and reliable in sedated ICU patients receiving mechanical ventilation?

## Methods

The study was nonexperimental and methodological.<sup>9</sup> The study was

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**Table 1** Data collection tool from the study of the Nonverbal Pain Scale<sup>a</sup>

Categories	0	1	2	Pre-score	Intervention Score	Post Score
1. Face	No particular expression or smile	Occasional grimace, tearing, frown or wrinkled forehead	Frequent grimace, tearing, frown or wrinkled forehead			
2. Activity (movement)	Lying quietly, normal position	Seeking attention through movement of slow cautious movements	Restless activity and/or withdrawal reflexes			
3. Guarding	Lying quietly, no positioning of hands over areas of body	Splinting areas of the body, tense	Rigid, stiff			
4. Physiologic I (vital signs)	Stable vital signs, no change in past 4 hours	Change over past 4 hours in any of the following: SBP >20 HR >20 RR >10	Change over past 4 hours in any of the following: SBP >30 HR >25 RR >20			
5A. Respiratory	Baseline RR/Spo <sub>2</sub> Complaint with ventilator	RR >10 above baseline or 5% ↓ Spo <sub>2</sub> Mild asynchrony with ventilator	RR >20 above baseline or 10% ↓ Spo <sub>2</sub> Severe asynchrony with ventilator			
5B. Physiologic II	Warm, dry skin	Dilated pupils, perspiring, flushing	Diaphoretic, pallor			
<b>5A TOTAL</b>						
<b>5B TOTAL</b>						

Abbreviations: HR, heart rate; RR, respiratory rate; SBP, systolic blood pressure; Spo<sub>2</sub>, oxygen saturation as measured by pulse oximetry.

<sup>a</sup> Reprinted with permission of Strong Memorial Hospital, University of Rochester Medical Center, developer and copyright holder of the scale.

given exempt status from the institutional review board at Creighton University Medical Center Hospital and Creighton University School of Nursing because all the patients were incapable of self-reporting their pain or providing informed consent for participation. The patients faced no additional risk because this research involved traditional nursing care procedures such as suctioning or repositioning a patient and the research was gathered by using observational data only. Each patient's privacy and confidentiality were protected by assigning a case number to each patient's data.

### Sample

The sample was a convenience sample of patients in the ICU at Creighton University Medical Center Hospital. The ICU is a 25-bed unit that primarily serves trauma and surgical patients. Subjects were at least 19 years old and were unable to verbalize or otherwise indicate pain by using a traditional scale. Patients excluded from the study were those receiving paralytic medications such as cisatracurium besylate or vecuronium bromide and those patients who were paralyzed without the use of medications or had been declared brain dead.

### Procedures

Data collectors were individually trained by the principal investigator (A.M.K.), who provided raters with a PowerPoint presentation that included criteria for selecting appropriate patients for the study and the data collection tool. The presentation contained the inclusion and exclusion criteria. During the training session, each rater practiced using the tool with the principal investigator. Once each nurse was comfortable and had achieved 90% interrater agreement with the principal investigator, the nurse was allowed to participate in the study.

.....

Data were entered by an administrative assistant who had been trained about the Health Insurance Portability and Accountability Act.

The data were collected by 9 registered nurses, 2 men and 7 women, in the ICU. Among the nurses, 2 had associate's degrees, 3 had nursing diplomas, 3 had bachelor's degrees, and 1 had completed graduate level classes. Three of these nurses were charge nurses. Of the 9 nurses, 3 worked the night shift, and 6 worked the day shift. The nurses had from 1 year to more than 20 years of experience working in an ICU. Two were men, and 7 were women. A total of 87% of the data (105 of 121 paired observations) was collected by the principal investigator, and the 3 charge nurses together accounted for 67% of the data collected (81 of the 121 paired observations). All patients were assessed 3 times: before, during, and at rest after a painful nursing procedure. For each patient, initial assessment at rest was immediately before the painful stimulus, and further observations were made during the procedure. Follow-up assessment was done 2 to 10 minutes after the painful stimulus.

A data collection tool was created that combined the original NVPS<sup>6</sup> items with the revised item from the NVPS.<sup>4</sup> This tool (Table 1) included the 4 common items: activity/movement, facial expression, guarding, and physiologic I (vital signs). It also included both the original physiologic II item and the revised (respiratory/ventilator compliance) item. This combination provided a simple 6-item data collection tool that could be analyzed by comparing the contributions of the 5 pain items of the

original with the added revised item (Table 1). This combined tool was chosen over using 2 distinct forms of the tool because the combined form was simpler for the raters and less likely to lead to reluctance of the busy ICU nurses to participate in the study. Because only a single item was changed in the revised instrument, it was deemed redundant to collect data on the other 4 identical items twice. This method was consistent with traditional methods of scaling and ranking based on the amount of a construct (pain) with an additional item that rates pain in the same manner, from lower to higher on a 3-point ordinal scale. This adjustment is equivalent to a monotonic scale calibration and should not affect results.<sup>10</sup> Statistical consultation supported the notion that researchers use many related items in validating a scale by ensuring that the number of subjects per item is adequate and subsequently eliminating any inadequate item or items. This process is called item analysis or reliability analysis in classical test theory.<sup>11</sup> Special software (which was not available) is needed to test the complex correlation, so the correlation between the original and the modified versions was calculated, and SPSS (SPSS Inc, Chicago, Illinois) software was used to detect any significant positive correlation.

A total of 121 independent observations by pairs of nurses on 64 different patients in the ICU were used for data analysis. For observations, pairs of nurses independently rated the same patient. Some patients were observed and rated more than once.

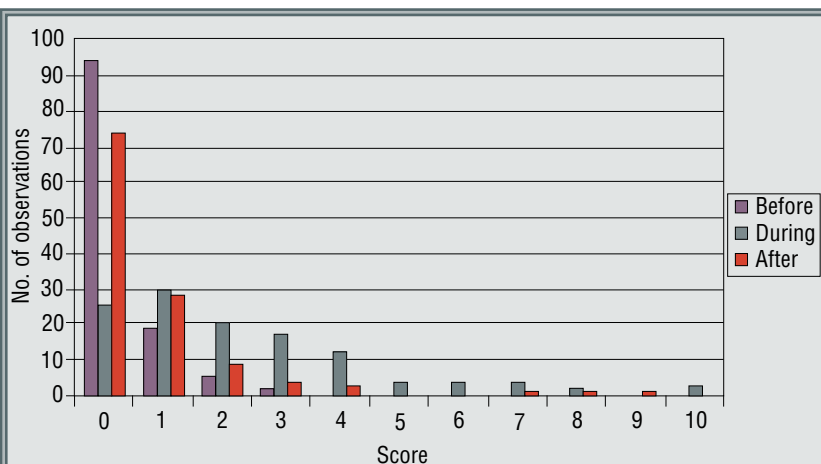
## *Data Analysis*

Interrater reliability was established by percent agreement procedures. For each set of concurrent observations, the difference between raters on the total score for the original NVPS and for the revised NVPS was calculated. When the difference was 0 or 1, the percent agreement was determined to be within 90%.

Internal consistency of both the original and revised NVPS was measured to determine if the 5 items on each scale and the total scale were consistently measuring discomfort in patients. In addition, the correlation of each item to the relevant total scale score was computed. The Cronbach  $\alpha$  was calculated for the data collected before, during, and after the painful stimulus. Item to total correlations were also used to explore internal consistency. Spearman correlation was used because of the skewed distribution of the data (Figure 1).

Hypothesis testing of relationships is an accepted approach to testing construct validity.<sup>9</sup> The theoretical construct, NVPS pain observations, was tested by hypothesizing predicted relationships between pain ratings of patients at rest and during a discomfort-inducing procedure (suctioning or repositioning). The hypothesis tested was that observations of pain ratings at rest would be significantly lower before a distressing procedure than during the procedure and would decrease approximately 2 to 10 minutes after the procedure.

Construct validity was assessed by using the Friedman repeated-measures test (the nonparametric analogue of repeated-measures analysis of variance) to test whether



**Figure 1** Distribution of pain ratings.

the hypothesized differences in ratings occurred among the 3 times (before, during, and after the intervention). An advantage of a repeated-measure (also called dependent or correlated measures) design is that each person serves as his or her own control, decreasing error variance and yielding a more powerful test with the specific sample size. Because of the skewed nature of the data, analysis of variance with repeated measures would not have been

appropriate. The Wilcoxon signed rank test was used for post hoc testing to examine where (between which ratings) the differences were significant. Table 2 is a glossary of statistical terms with source citations<sup>9,12</sup> used in this section. All analyses were done separately on the original and revised versions of the NVPS.

## Results

Interrater reliability assessments met the 90% agreement criterion in

most of the comparisons. On a subset of 76 concurrent observations by 2 nurses, agreement of at least 90% was achieved on 72 observations (94.7%) with the original NVPS and on 69 observations (90.8%) with the revised NVPS.

Testing of the original scale resulted in internal consistency as indicated by Cronbach  $\alpha$  values of 0.36 (prior), 0.62 (during), and 0.62 (after). The revised scale resulted in  $\alpha$  values of 0.36 (prior), 0.72 (during), and 0.71 (after). Spearman item to total correlations (Table 3) showed moderate correlations for most of the items with their respective scale. Correlations between the physiologic II item and the original NVPS were quite low. This result is congruent with the finding by Odhner et al<sup>6</sup> that this item had the lowest correlation to the total scale.

Both the original and the revised NVPS showed significant differences between the ratings from before, during, and after the painful stimulus (original, 135.86,  $P < .001$ ,  $n = 121$ ;

**Table 2** Glossary of terms

Cronbach $\alpha$	Measures the extent to which items go together and identifies those items that contribute little to the overall measurement score; known as internal consistency reliability Internal consistency measures of 0.70 and above considered adequate <sup>12</sup>
Construct validity	Refers to the extent to which an instrument actually measures the theoretical construct that is intended by testing predicted relationships, convergent or divergent relationships, or outcome of contrasted groups <sup>9</sup>
Friedman's repeated-measures test	A nonparametric test of variance used appropriately when the same subjects are measured repeatedly under different conditions; similar to use of analysis of variance for data that meet parametric assumptions <sup>12</sup>
Kendall's $\tau$	A nonparametric test of the relationship between 2 ranked (ordinal) variables <sup>12</sup>
Nonparametric statistics	Statistical procedures for analysis of data that do not meet the assumptions for parametric statistics (eg, are not randomly selected) at the interval or ratio level of measurement or are not normally distributed/are skewed <sup>9</sup>
Item to total correlation	A statistical procedure to identify items in a scale that are not related to the other items in the scale <sup>12</sup>
Wilcoxon signed rank test	A nonparametric statistic to test for differences between two matched pairs of ranked samples; comparable in use to the paired $t$ test for parametric data <sup>12</sup>



**Table 3** Item to total correlations (Spearman correlation)

	Item					
	Face	Activity	Guarding	Physiologic I	Respiratory	Physiologic II
Original						
Before intervention	0.835	0.554	0.303	0.291	—	0.219 <sup>a</sup>
During intervention	0.708	0.657	0.639	0.557	—	0.257
After intervention	0.607	0.440	0.430 <sup>a</sup>	0.724	—	0.277
Revised						
Before intervention	0.809	0.542	0.300	0.306	0.332	—
During intervention	0.648	0.588	0.663	0.577	0.689	—
After intervention	0.585	0.415	0.422	0.703	0.554	—

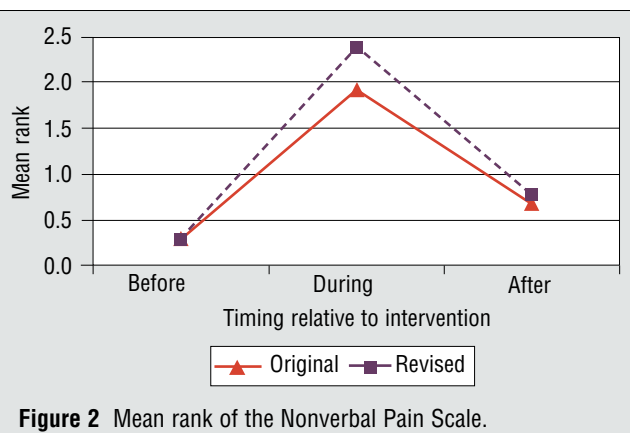
<sup>a</sup> Correlation is significant at the .05 level (2-tailed). All other correlations are significant at the .01 level (2-tailed). Dashes indicate not applicable.

revised, 145.05,  $P < .001$ ,  $n = 121$ ). Figure 2 shows the mean ranks from the nonparametric Friedman's repeated-measures test for each time for both scales. Post hoc testing showed that for both scales and every individual item, the pain rating during the intervention was significantly higher than the pain rating before or after the intervention with a single exception. Ratings on the physiologic II item did not increase significantly as expected during the painful procedure. Figure 3 shows the mean rank for this item compared with the respiratory item, which is the item that replaced it in the revised NVPS.

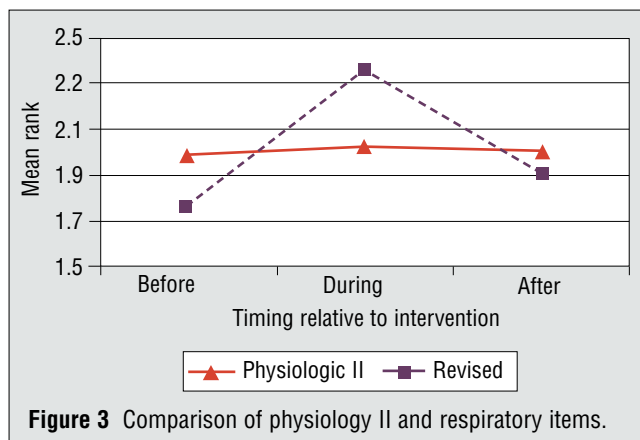
## Discussion

Both total scales were supported for overall construct validity (Figure 2). However, as seen in Figure 3, the construct validity of the respiratory category is supported by the changes shown from before, during, and after, whereas the physiologic II category showed little variation. This result indicates that the physiologic II item was not discriminatory at an acceptable level. This finding supports

the decision of Wegman<sup>4</sup> to substitute the respiratory item in the revised version. Reliability of both versions was acceptable for the scores obtained during and after painful interventions. Internal consistency as indicated by the Cronbach  $\alpha$  was a little better for the revised version. Although the original version had 1 item-to-total correlation that was slightly higher than in the revised version, the low item-to-total correlation of the physiologic II item also supported the superiority of the revised version. These findings tend to support the use of the revised NVPS rather than the original NVPS.



**Figure 2** Mean rank of the Nonverbal Pain Scale.



**Figure 3** Comparison of physiology II and respiratory items.

## Limitations

The development of nonverbal pain instruments for sedated ICU patients receiving mechanical ventilation is at an early stage, and the complex clinical environment and patient conditions presented difficulties in measurement and in control

in our study. The NVPS has previously been tested in only 1 other hospital. An additional area for concern is that the data collectors were aware of the stage (before, during, or after the intervention) when they completed their ratings. This knowledge could have influenced their scoring on the 3 observational items (face, activity, guarding) because they may have expected the scores to be higher during the intervention. This possible bias is potentially problematic because the main finding that supports the construct validity of the scale is that the scores increased significantly during the painful procedure. Psychometric consultation should be considered for studies that test complex, observational measurements.

#### Implications for Practice

Accurate assessment and pain management are essential to quality patient care. The Joint Commission standards of care underscore the

importance of these practices. Our findings support the revised NVPS as a potentially valid and reliable observational tool for assessing pain in this ICU population of patients who are sedated and receiving mechanical ventilation but not paralyzed. Because the NVPS has been validated in only 1 other published study, the tool should be further tested in new ICU populations for validity and reliability.

Implementation of a new practice in any setting requires careful planning, staff involvement and motivation, training, and resources. For instance, it would be important to have laminated cards (Table 4) with the revised NVPS, or any nonverbal pain scale, at the bedside or taped to the head of the bed to remind nurses of the rating scale and the policy for pain assessment. Regular monitoring and feedback by a designated change agent and problem solver would be useful to maintain and institutionalize the

practice until it becomes part of standard care.

#### Implications for Future Research

Additional research in ICU patients may also be useful to compare mean ratings of alert, observed patients on the NVPS with the corresponding self-reports of these same patients on a 0 (no pain) to 10 (most severe pain) numeric scale. Such research may be useful to test the construct validity of the tool further and might permit estimations of mild, moderate, or severe pain. It would also be useful to compare the NVPS with any other published nonverbal scales designed for use in ICU patients receiving mechanical ventilation.

Another promising observational tool for assessing pain in sedated ICU patients receiving mechanical ventilation, the BPS, is valid and reliable.<sup>5</sup> Nurses using the BPS rate facial expressions from 1 (relaxed) to 4 (grimacing), upper limb movement from 1 (no movement) to 4

**Table 4** Revised card for Nonverbal Pain Scale<sup>a</sup>

	0	1	2	Score
1. Face	No particular expression or smile	Occasional grimace, tearing, frown or wrinkled forehead	Frequent grimace, tearing, frown or wrinkled forehead	
2. Activity (movement)	Lying quietly, normal position	Seeking attention through movement of slow cautious movements.	Restless activity and/or withdrawal reflexes	
3. Guarding	Lying quietly, no positioning of hands over areas of body	Splinting areas of the body, tense	Rigid, stiff	
4. Physiologic I (vital signs)	Stable vital signs, no change in past 4 hours	Change over past 4 hours in any of the following: SBP >20 HR >20 RR >10	Change over past 4 hours in any of the following: SBP >30 HR >25 RR >20	
5. Respiratory	Baseline RR/Spo <sub>2</sub> Complaint with ventilator	RR >10 above baseline or 5% ↓ Spo <sub>2</sub> Mild asynchrony with ventilator	RR >20 above baseline or 10% ↓ Spo <sub>2</sub> Severe asynchrony with ventilator	
<b>Revised Nonverbal Pain Scale (NVPS)</b>				<b>Total</b>

Abbreviations: HR, heart rate; RR, respiratory rate; SBP, systolic blood pressure; Spo<sub>2</sub>, oxygen saturation as measured by pulse oximetry.

<sup>a</sup> Reprinted with permission of Strong Memorial Hospital, University of Rochester Medical Center, Rochester, New York, developer and copyright holder of the scale.



(fully retracted), and ventilator compliance from 1 (tolerant of movement) to 4 (unable to control ventilation), yielding ratings from 3 to 12. Our research council was uncomfortable with the absence of any physiological indicator on the BPS and also with the rating scale from 3 to 12 because nurses were accustomed to pain ratings from 1 to 10. The council members also thought that the use of 2 different scales, with different values, in the same unit would be confusing, even though they realized that observational ratings were not equivalent to self-reported intensity ratings. More recently, 2 additional validation studies<sup>13,14</sup> of the BPS, in Moroccan and Australian populations, have been reported. The Moroccan study<sup>13</sup> was not available, but the investigators in the Australian study<sup>14</sup> assessed the validity of the BPS by comparing painful (repositioning) and not painful (eye care) procedures in ICU patients. The validity of the ratings was supported by descriptive findings that 73% of the BPS scores increased significantly during and after the painful procedures ( $P < .003$ ), but only 14% of the scores increased after the eye care procedures ( $P = .36$ ). Nurses selecting a pain scale for use in the ICU for sedated patients receiving mechanical ventilation might want to compare the NVPS and the BPS

directly by testing these 2 scales in their patients. **CCN**



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#### Acknowledgments

We thank Jeff Allen, James Pullen, Pat Le, Carla Hohn, Jill Danahay, Wendy Siegel, Lori Conroy, and Michelle Rude for all their help collecting data. We also thank Kim Good for her efforts in data entry.

#### Financial Disclosures

None reported.

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To learn more about pain scales, read "Duration of Mechanical Ventilation in an Adult Intensive Care Unit After Introduction of Sedation and Pain Scales," by Teresa Ann Williams et al in the *American Journal of Critical Care* 2008;17:349-356. Available at [www.ajcconline.org](http://www.ajcconline.org).

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## Assessing pain in non-intubated critically ill patients unable to self report: an adaptation of the Behavioral Pain Scale

Received: 29 April 2009  
Accepted: 7 July 2009  
Published online: 21 August 2009  
© Springer-Verlag 2009

### Electronic supplementary material

The online version of this article (doi:[10.1007/s00134-009-1590-5](https://doi.org/10.1007/s00134-009-1590-5)) contains supplementary material, which is available to authorized users.

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**Abstract** *Purpose:* To validate an adaptation of the Behavioral Pain Scale (BPS) for its use in non-intubated intensive care unit (ICU) patients unable to self-report their pain because of the occurrence of delirium. The "vocalization" domain was inserted to construct the BPS-non intubated (BPS-NI) scale, ranging from 3 (no pain) to 12 (most pain). *Design:* Prospective psychometric study in a medical-surgical ICU. *Methods:* The same physician and one bedside nurse rated pain in non-intubated patients unable to self-report their pain during four conditions: before and after a catheter dressing change (non-nociceptive procedure) and before and after turning the patient (nociceptive procedure). Delirium was assessed by the Confusion Assessment Method for the ICU (CAM-ICU). *Results:* A total of 120 paired evaluations were performed in 30 consecutive adult patients, 84% with delirium

(CAM-ICU positive). BPS-NI scores were higher during painful procedures than at rest [6.0 (5.0–8.0) vs. 3.0 (3.0–3.8);  $P < 0.001$ ], while no changes in BPS-NI scores were found during non-nociceptive procedures (discriminative validity). The BPS-NI had good internal consistency (standardized Cronbach  $\alpha = 0.79$ ), and each domain reflected the pain expression factor in a balanced way (coefficients between 0.57 and 0.59). The BPS-NI had a good inter-rater reliability (weighted kappa coefficient = 0.89 for the four conditions and 0.82 during nociceptive procedures) and a good responsiveness, with an effect size ranging from 1.5 to 3.6. *Conclusions:* Pain during procedures is perceived even in non-intubated ICU patients with delirium. In those patients, pain level can be assessed with the BPS-NI scale since this instrument exhibited good psychometric properties.

**Keywords** Pain · Pain measurement · Analgesia · Delirium · Psychomotor agitation · Intensive care · Critical care

## Introduction

Pain is common in intensive care unit (ICU) patients, with an incidence up to 50% in surgical, as well as medical, patients [1, 2]. It has been shown that better management of pain in both intubated and non-intubated ICU patients, including a systematic evaluation of pain intensity and a therapeutic strategy of analgesic prescription, has been associated with improved outcome [3]. In this study, the median proportion of patients assessed using the self-administered Numerical Rating Scale (NRS) was 70% in non-intubated patients, contrasting with 100% of intubated patients assessed using the Behavioral Pain Score (BPS) administered by nurses. Indeed, pain assessment using a self-report scales (Visual Analogue Scale, NRS), as recommended in the general population [4–6], is not always possible in patients with altered neurological status.

There is no clinical tool to assess pain for non-intubated, non-communicating ICU patients, i.e., patients with delirium and/or an impaired vigilance status [7, 8]. To our knowledge, only the Critical Care Pain Observation Tool (CPOT) has been validated for mechanically ventilated and non-ventilated cardiac surgery patients [9]. This score has also been validated for mechanically ventilated, medical-surgical patients [10], but not for a mixed medical-surgical population of non-intubated ICU patients, and particularly not for ICU patients with delirium. Although similar, this four-domain score is distinct from the BPS, which is a score of only three behavioral domains, including facial expression, upper limb movements and compliance with ventilation. The BPS was initially elaborated to assess pain in nonverbal, mechanically ventilated patients with no severe head injury [11–13]. Because each domain of the BPS contains four descriptors instead of three for the CPOT, the BPS avoids a possible observer bias described when an observer rates preferentially the middle item of a three-point scale [14]. Use of the BPS is gaining interest in France and other countries [1, 13, 15].

The objective of this study was to construct and validate a new pain instrument devoted to non-intubated ICU patients (BPS-NI) unable to self-report their pain. We switched the “compliance with ventilation” domain of the initial BPS to a “vocalization” domain in this new form of BPS for non-intubated patients (BPS-NI). The choice of this domain was derived from Thunder Project II [16]. This study determined that vocal behavior was the most common pain behavior associated with the facial expression and the tonus of limbs. Vocal behavior was described as moaning, screaming, verbal complaints of pain and use of protesting words [16]. A vocalization domain of the BPS was then constructed and combined with the two other domains of the initial BPS.

## Materials and methods

Detailed methods are provided in the Electronic Supplementary Material (ESM).

The present observational psychometric study took place in a 16-bed medical–surgical ICU. During a 7-month period, all consecutive patients  $\geq 18$  years old and staying in the ICU for more than 24 h were eligible if they were (1) non-intubated or non-tracheotomized and (2) unable to self-report pain using a 0–10 enlarged NRS. This scale was adapted to ICU patients, who often suffer from sensorial deficiencies, by enlarging the printed scale to make it easily visible ( $10 \times 30$  cm) [3, 16]. Exclusion criteria were postoperative patients without any complications or organ dysfunctions, patients with severe brain injuries, quadriplegia, or history of severe dementia and mental retardation.

The scientific and ethics committee of the Comité d’Organisation et de Gestion de l’Anesthésie Réanimation du Centre Hospitalier Universitaire de Montpellier (COGAR) approved the design of the study. Because of the strictly observational study design and the absence of modification in clinical management of patients, the need for written consent from the patient or his relatives was waived.

### Construction of the BPS adapted to non-intubated patients (see ESM)

The BPS evaluates three behavioral domains (i.e., facial expression, movements of upper limbs and compliance with ventilator). Each domain contains four descriptors that are rated on a 1–4 scale, and the total BPS value can range from 3 (no pain) to 12 (most pain) [11]. Training of nurses in the use of BPS has been evaluated several times in the unit for the reliability of their measurements [3]. The objective of the present study was to construct and validate a new tool, adapted from the original BPS to the non-communicant, non-intubated patient (BPS-NI). Like other pain scales, the BPS-NI can be used by caregivers to assess pain, for usual clinical practice or clinical research, several times a day, at rest and during nociceptive procedures. The procedure for using the BPS was estimated to take minimal time (2–5 min) [11]. Figure 1 shows the training poster of global BPS including the original BPS and the BPS-NI. The vocalization domain was described as “no pain vocalization,” “infrequent moaning ( $\leq 3$ /mn) and not prolonged ( $\leq 3$  s),” “frequent moaning ( $> 3$ /mn) or prolonged ( $> 3$  s),” and “howling or verbal complaints including Ow!, Ouch! or breath-holding.” Assessment of the duration ( $\leq$  or  $> 3$  s) of moaning seems to be common for reference pain caregivers because of the routine use of the Richmond Agitation Sedation Scale (RASS) in the ICU [17–19] (see below). In that scale, the observer

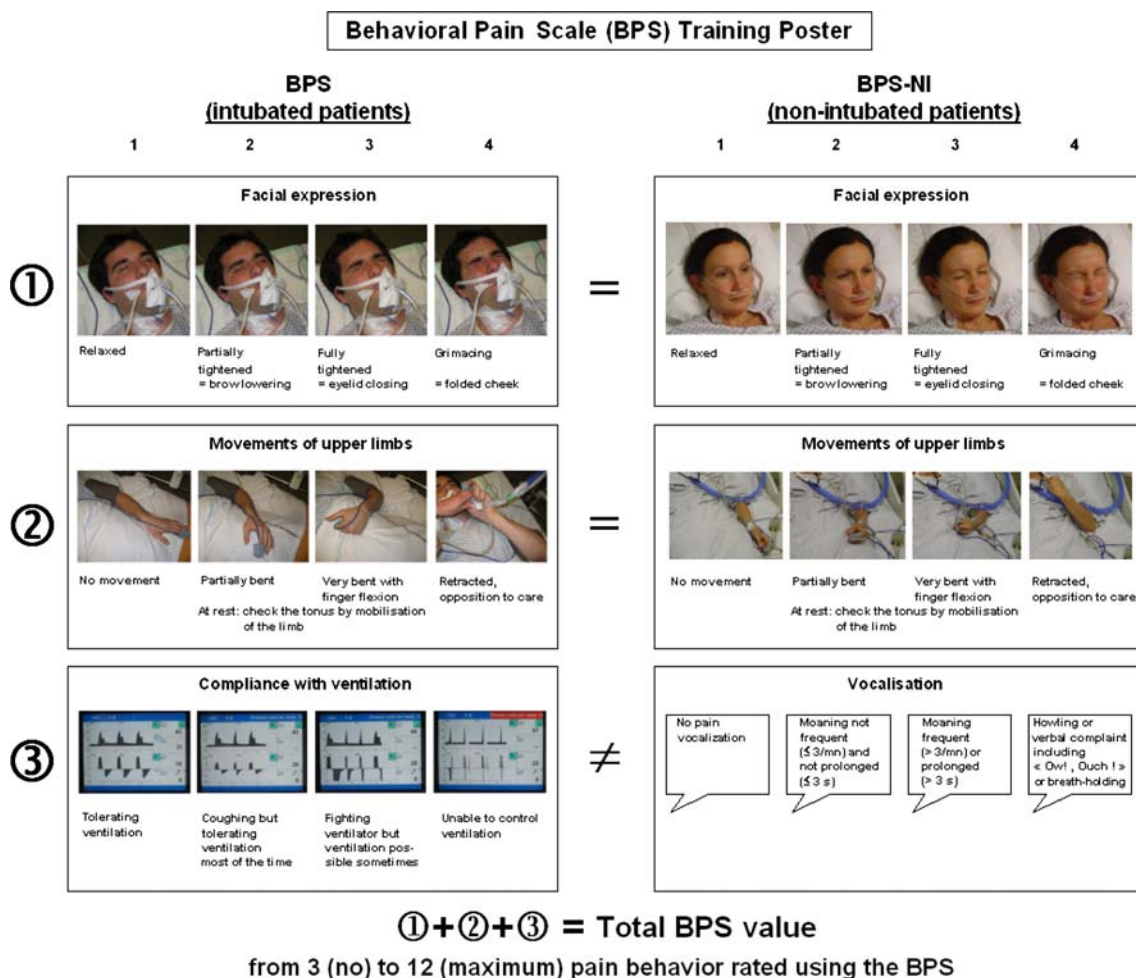
assesses the level of vigilance by measuring objectively the duration of eye contact as < or >10 s [17–19].

### Study validation of the BPS-NI (see ESM)

Consecutive non-intubated patients were evaluated each morning by the bedside nurse for their ability to self-report pain with the NRS. If the patient failed to pass the test for two evaluations within a 4-h period, the bedside nurse contacted the pain referent physician (PRP) who attempted to evaluate the pain using the NRS. Patients able to rate their pain were not eligible for the study. The other patients, those who were unable to rate their pain, even with the assistance of the PRP (see ESM), were

included in the study. The presence of delirium was checked by the PRP using the Confusion Assessment Method for the ICU (CAM-ICU) [20, 21]. We hypothesized that inattentiveness, disorganized thinking and/or an impaired vigilance status could explain, in part, the inability of the patient to use a 0–10 NRS. During the CAM-ICU procedure, the level of vigilance was measured using the RASS, which is the only vigilance scale validated in both ventilated and non-ventilated ICU patients [17–19]. Other reasons for the inability of the patient to self-report his/her pain included neurological and psychological disorders, such as impaired vigilance status, delusion, language disorders or incomprehension.

After neurological and psychological examination, the BPS-NI evaluation was independently performed



**Fig. 1** Behavioral Pain Score training poster. This figure is a guide to training nurses and physicians to use the Behavioral Pain Score (BPS) in the ICU. The BPS, which was previously described and validated in non-communicating, mechanically ventilated patients, is extended in the present study to non-communicating, non-intubated or non-tracheotomized patients (BPS-NI). The first two domains are the same for the BPS and BPS-NI (i.e., facial expression and upper limbs movements). The third domain is

different according to the mechanical ventilation status: compliance with ventilation (BPS) or vocalization (BPS-NI). The BPS and BPS-NI can be used by caregivers to assess pain in ICU non-communicant patients, for usual clinical practice or clinical research, like other pain scales, several times a day, at rest and during nociceptive procedures. The procedure for using the BPS was estimated to take minimal time (2–5 min) [11]. The ESM includes the original high-definition picture of this poster



within a working day at the same time by two paired evaluators (the PRP and bedside nurse) in four conditions for each patient: (1) at rest before and (2) during a non-nociceptive procedure (dressing change of a central venous catheter or an arterial catheter); (3) at rest-before and (4) during a nociceptive procedure (turning of the patient for the toilet and the massage of back and pressure points). This last procedure was considered the most common nociceptive procedure in the ICU setting [16]. For all of these measurements, the PRP was blinded to the BPS-NI values obtained by the other raters, i.e., the bedside nurses. Physiological parameters (heart and respiratory rates, mean arterial blood pressure and pulse oxymetry) were measured continuously and recorded by the PRP.

#### Statistical analysis (see ESM)

The validation of an instrument measuring a subjective variable (like pain) requires a comparison with a gold standard. In the absence of such a gold standard for non-intubated ICU patients who were unable to communicate, we had to validate the BPS-NI with indirect arguments, which consisted of checking the psychometric properties of validity, reliability and responsiveness according to standard definitions [22, 23] (see ESM). Methods of previous studies that validated the BPS in mechanically ventilated patients were used [11, 12]. The validity of the BPS-NI was tested in three ways (see ESM): by discriminative validity, internal consistency using the Cronbach  $\alpha$  method [24] and factor structure by performing exploratory principal component factor analysis to determine the contribution of each item [25]. Only the BPS-NI evaluations performed by nurses were included for these analyses. Physiological parameters were analyzed by nonparametric tests. The inter-rater reliability of the BPS-NI was tested by the weighted kappa coefficient and by the correlation of the BPS-NI values observed by the nurses and the PRP, measured by the Spearman's test (see ESM). The inter-rater agreement within an error of one mark was calculated as the ratio, expressed in percentage, between the number of the BPS-NI values different by more than one point between nurses and the PRP, and the total number of the BPS-NI paired values. Finally, the responsiveness of the BPS-NI was assessed by the effect size analysis [26] (see ESM).

Quantitative data were shown as medians and 25–75th percentiles. Significance for all statistical tests was set at  $P < 0.05$ . The sample size required for validation of the BPS-NI was established using the precision of a coefficient, such as Cronbach  $\alpha$  [27]. Thus, with a precision of Cronbach  $\alpha$  of  $0.90 \pm 0.05$  as an objective, and for a value of three domains, it was required to include 30 patients in the study [12, 27].

Data were analyzed using the SAS software version 9.1 (SAS Institute, Cary, NC) by an independent confirmed statistician (GM).

## Results

Among the 290 patients admitted to the ICU during the period of the study, 107 were excluded because they were postoperative patients without any complications or organ dysfunctions ( $n = 96$ ) or died before extubation ( $n = 11$ ). Among the 183 remaining patients who were not intubated or extubated during their ICU stay, 37 (20%) were unable to self-report their pain with the NRS. Of these, seven patients were excluded because of a history of mental retardation ( $n = 2$ ), severe dementia ( $n = 2$ ), stroke ( $n = 1$ ), post-anoxic coma ( $n = 1$ ) and cranial trauma ( $n = 1$ ). Patient demographics are shown in Table 1. The impossibility for the patients to self-report their pain was mainly delirium ( $n = 25$ ). The BPS-NI was tested by 18 of the 35 nurses and 15 of the 20 assistant nurses. All the nurses had several months of work experience in the unit. The 30 patients were evaluated for the four conditions during a working day. In all, 240 BPS-NI evaluations were performed. The 120 BPS-NI values measured by nurses were compared with the 120 BPS-NI values observed by the PRP.

#### Validation study

The median BPS-NI value significantly increased from rest to nociceptive procedure [3.0 (3.0–3.8) vs. 6.0 (5.0–8.0),  $P < 0.001$ ]. Contrary to the nociceptive procedure, the median BPS-NI value did not increase significantly during the non-nociceptive procedure [3.0 (3.0–3.8) vs. 3.0 (3.0–4.0),  $P = 0.11$ ] (Fig. 2). These findings constitute a discriminative validation of the BPS-NI.

Cronbach  $\alpha$  values indicated that the BPS-NI had good internal consistency (raw Cronbach  $\alpha = 0.77$ , standardized Cronbach  $\alpha = 0.79$ ), meaning that the three domains of the BPS-NI were well correlated between them.

Using exploratory principal component factor analysis, we found a large first factor, which accounted for 71% of the variance in pain expression, with a strong correlation of the domains with this factor, including coefficients of 0.59 for facial expression, 0.57 for upper limb movements and 0.57 for vocalization. In other words, this statistical method provided a mathematical and single surrogate value containing 71% of the information of the three domains of the BPS-NI and quantified the weight of each domain. These findings imply that all three domains of the BPS-NI were interrelated and reflected a pain expression factor in a balanced way.

**Table 1** Demographics of the 30 patients included for analysis

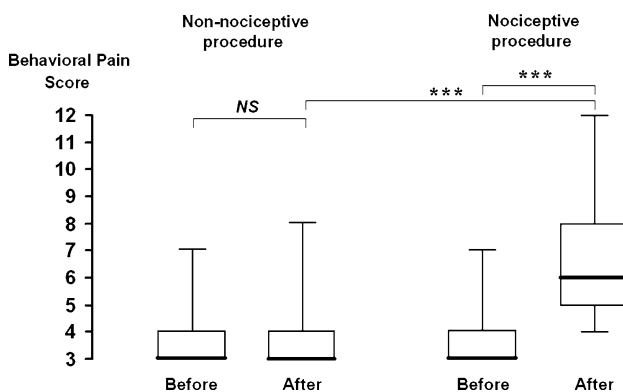
<i>Demographics at time of admission to ICU</i>	
Age (years)	69 [60–78]
Sex (F/M)	10/20
Type of admission, <i>n</i> (%)	
Medical, <i>n</i> (%)	16 (53)
Surgical, <i>n</i> (%)	14 (47)
SAPS II	55 [46–63]
SOFA	8 [6–12]
Mechanical ventilation, <i>n</i> (%)	23 (77)
Duration of mechanical ventilation (days)	3 [1–5]
Continuous infusion of sedatives, <i>n</i> (%)	17 (57)
Duration of infusion (days)	2 [2–3]
<i>Demographics at time of enrollment</i>	
Time between admission to ICU and enrollment (days)	4 [2–7]
SAPS II	37 [30–49]
SOFA	6 [4–6]
Infusion <sup>a</sup> of at least one analgesic drug, <i>n</i> (%)	11 (37)
Infusion <sup>a</sup> of at least one WHO step-2 or more, or similar effect analgesic drug <sup>b</sup> , <i>n</i> (%)	7 (23)
Acetaminophen, <i>n</i> (%)	6 (20)
Nefopam, <i>n</i> (%)	4 (13)
Tramadol, <i>n</i> (%)	4 (13)
Morphine, <i>n</i> (%)	1 (3)
Fentanyl, <i>n</i> (%)	1 (3)
Infusion <sup>a</sup> of at least one sedative drug, <i>n</i> (%)	3 (10)
Haloperidol, <i>n</i> (%)	2 (7)
Benzodiazepine, <i>n</i> (%)	2 (7)
<i>Vigilance status</i>	
Normal vigilance status (RASS level = 0), <i>n</i> (%)	13 (43)
Impaired vigilance status (RASS level <0), <i>n</i> (%)	13 (43)
Median RASS level when <0	–1 [–1, –1]
Increased motor activity (RASS level >0), <i>n</i> (%)	4 (14)
Median RASS level when >0	+3 [+ 2, +3]
<i>Reason for impossibility of the patients to self-report their pain</i>	
Delirium (CAM-ICU +), <i>n</i> (%)	25 (84)
Incomprehension, <i>n</i> (%)	3 (10)
Paranoid delusion, <i>n</i> (%)	1 (3)
Mutism, <i>n</i> (%)	1 (3)

Continuous data are expressed in median [25–75th percentiles]. ICU Intensive care unit, SAPS II Simplified Acute Physiological Score II value [36], SOFA Sequential Organ Failure Assessment value [37], RASS Richmond Agitation Sedation Scale [17–19], WHO World Health Organization, CAM-ICU Confusion Assessment Method for the Intensive Care Unit [20, 21]

<sup>a</sup> All the analgesic and sedative drugs listed below were administered intravenously

<sup>b</sup> WHO step-2 or more, or similar effect analgesic drugs used were: morphine and fentanyl (WHO step-3 analgesics), tramadol (WHO step-2 analgesic) and nefopam (non-opioid but at least as effective as a WHO step-2 analgesic drug) [38]

Finally, there were slight, but significant, increases in RASS level, heart rate and respiratory rate during nociceptive procedures compared to other procedures (Table 2). However, a clinically relevant change of physiological parameters during nociceptive procedures



**Fig. 2** BPS-NI observed by nurses during the four conditions. This figure shows that the median Behavioral Pain Score adapted to non-intubated patients (BPS-NI), observed by nurses in the 30 patients included in the study, increased significantly from rest to a nociceptive procedure, but not from rest to a non-nociceptive procedure. This constitutes the validation structure procedure of the BPS-NI (discriminative validity). Medians are expressed as *horizontal bars in bold*, 25–75th percentiles as *boxes* and maximal-minimal values as *vertical bars*. NS = Non significant; \*\*\* $P < 0.001$

was observed in less than 50% of patients (Table 2), whereas an increase of the BPS-NI of 2 or more points was measured in 25 patients (83%).

### Reliability study

The weighted kappa coefficient, calculated to estimate the magnitude of agreement between the bedside nurses and the PRP, showed an important to near perfect agreement (all weighted kappa coefficients above 0.6) (Table 3). The magnitude of agreement remained important when only nociceptive procedures were taken into account, i.e., for BPS-NI values above 3 (Table 2). This agreement was not less important for the vocalization domain compared to the two other domains (Table 2). Within an error of one point, inter-rater agreement was 96% for the BPS-NI scores for both types of procedures and 90% for the BPS-NI scores for nociceptive procedures only. The correlation of the BPS-NI values between nurses and PRP was strong ( $r^2 = 0.88$ ,  $P < 0.001$ ) (Fig. 3). A nociceptive procedure BPS-NI score greater than 5 was measured by the nurses in 20 patients (67%) and by the PRP in 22 patients (73%).

### Responsiveness study

The effect size for responsiveness was large for the three domains of the BPS-NI (facial expression = 2.82, upper limb movements 1.47, vocalization 3.64) and the total BPS values observed by the nurses (3.46).

**Table 2** Change of physiological parameters during the nociceptive procedures in the 30 patients included for analysis

	At rest	During a nociceptive procedure
Median values of physiological parameters		
MAP (mmHg)	83 [78–90]	88 [77–97]
Heart rate (b/min)	95 [79–104]	97 [85–106]*
Respiratory rate (b/min)	20 [17–25]	22 [20–26]*
Pulse oxymetry (%)	97 [96–100]	97 [96–99]
RASS level	0 [–1–0]	0 [0–0]*
Rate of patients with a clinically relevant change of physiological parameters during the nociceptive procedures, <i>n</i> (%)		
Increase MAP $\geq 10\%$ from rest value		9 (30)
Decrease MAP $\geq 10\%$ from rest value		4 (13)
Increase heart rate $\geq 10\%$ from rest value		7 (23)
Decrease heart rate $\geq 10\%$ from rest value		1 (3)
Increase respiratory rate $\geq 10\%$ from rest value		11 (36)
Decrease respiratory rate $\geq 10\%$ from rest value		4 (13)
Increase pulse oxymetry $\geq 2$ points from rest value		2 (6)
Decrease pulse oxymetry $\geq 2$ points from rest value		3 (10)
Increase RASS level $\geq 2$ points from rest value		2 (6)
Decrease RASS level $\geq 2$ points from rest value		0 (0)

Continuous data are expressed in median [25–75th percentiles]

MAP Mean arterial blood pressure, RASS Richmond Agitation Sedation Scale [17–19]

\**P* value < 0.05

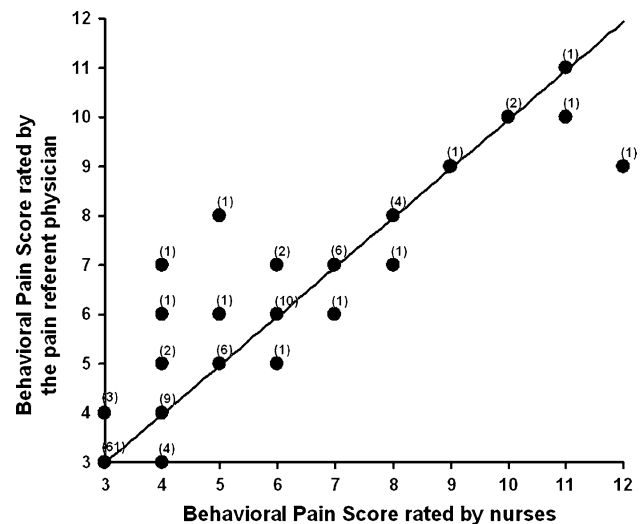
**Table 3** Magnitude of agreement for the Behavioral Pain Score-Non Intubated between bedside nurses and the pain referent physician measured by the weighted kappa test

Condition	Weight kappa coefficients [95th confidence limits]			
	Total Behavioral Pain Score-Non Intubated	Facial expression domain	Upper limbs movements domain	Vocalization domain
All the four conditions	0.89 [0.84–0.94]	0.83 [0.75–0.92]	0.79 [0.69–0.90]	0.93 [0.87–0.98]
Nociceptive procedures only	0.82 [0.69–0.95]	0.80 [0.63–0.97]	0.62 [0.34–0.91]	0.89 [0.79–0.99]

## Discussion

The BPS adapted to non-mechanically ventilated, non-intubated critically ill patients unable to self-report their pain (BPS-NI) is a valid, reliable and responsive instrument to measure pain in this population. The BPS-NI and the CAM-ICU could be used together to assess the patient's pain and confusion, respectively.

A similar discriminative validity of BPS was shown in previous studies that measured the psychometric properties of BPS [11, 12], for which the mean value increased significantly from 3.0 at rest to 4.9 during a nociceptive procedure [11] and from 3.7 to 6.8 [12]. A similar large first factor was reported in previous studies [11, 12]. However, contrary to the two studies, which found a lower coefficient of correlation between the first factor and the domain of compliance with ventilation, in the present study we found a very well-balanced correlation between the first factor and all three domains. This could be explained by the modification of the third domain (i.e., “compliance-with-ventilation”), which was changed to “vocalization” in non-intubated patients. Compared to physiological parameters, the BPS-NI value changed



**Fig. 3** Correlation between the BPS-NI values observed by nurses and the pain referent physician. This figure shows a strong correlation between the Behavioral Pain Score adapted to non-intubated patients (BPS-NI) observed by nurses and BPS-NI observed by the pain referent physician ( $r^2 = 0.88$ ,  $P < 0.001$ , Spearman's test). Each number reflects how many results were observed per paired assessments



more often during nociceptive procedures. Previous studies have shown that hemodynamic parameters were a poor surrogate to evaluate pain compared to behavioral tools [11, 12]. The complex pathology and important deregulation of physiology observed in critically ill patients could explain these findings [28].

The inter-observer reliability of BPS in the present and previous studies is high. Aïssaoui et al. [12] found an intraclass correlation coefficient of 0.95 and Payen et al. [11] a weighted kappa coefficient of 0.74. The very high coefficients measured in the previous and present studies, even taking into account only the nociceptive procedures, could be explained by the extensive training and experience of the ICUs in pain assessment. Finally, the responsiveness of the BPS was previously measured using the effect size coefficient, which ranged from 2.2 to 3.4 for the total BPS value [12], similar to the results of the present study (3.46).

Since the review of pain measurement instruments available in the ICU setting by Hamill-Ruth and Marohn 10 years ago [7], which highlighted the absence of validated instruments for the critically ill patients who are often unable to communicate, aside from the COMFORT scale for children [29], several new behavioral pain instruments have been described in the literature [9, 11, 16, 30–33]. However, a recent review [8] of all these instruments concluded that only the BPS [11] and the CPOT [9] have been shown to provide acceptable levels of validity and reliability. Aside from the BPS-NI validated by the present study, to our knowledge, no pain measurement instruments have been evaluated for use in non mechanically ventilated medical-surgical ICU patients with delirium and unable to self-report their pain.

Our study has several limitations. The main limitation is that the validation study used an indirect method to assess pain in the absence of an objective pain measurement reference. Secondly, as in similar studies [11, 12, 17, 18, 34, 35], it was impossible to blind nociceptive and non-nociceptive conditions. Thirdly, because of the aim of this study, performed in a single center with a small number of patients, was to measure the psychometric properties of the BPS-NI, further studies are needed to show the transferability of this tool to other teams and the clinical impact of the use of such instruments, as this

would probably constitute the most pertinent validation of an instrument. To our knowledge, only one study has demonstrated positive clinical results through use of the BPS to manage pain in ICU patients at rest [3]. However, 30% of scheduled assessments of pain were not performed in non-intubated patients. The absence of an available pain measurement instrument for non-intubated, non-communicating patients is likely the cause for this lack of assessment. This study's findings may have been more pertinent if a "universal" BPS had been used, such as the BPS-NI of the present study, in conjunction with the original one. The moderate use of at least World Health Organization step 2 or more, or similar effect analgesic drugs observed in the present study at rest (23%), could be greater, such as their use during nociceptive procedures, after the implementation of a BPS-NI based analgesia protocol.

Finally, although we included mainly patients with delirium, we did not validate this score in patients with a large impaired vigilance status. However, it is likely that many of these patients, for example, comatose patients, would require intubation.

In conclusion, the Behavioral Pain Scale-Non Intubated (BPS-NI), an adaptation of the original BPS for non-mechanically ventilated critically ill patients who are unable to self-report their pain, such as patients with impaired vigilance status and/or delirium, is a valid, reliable and responsive instrument to measure pain in this population of ICU patients. This pain scale could be used by caregivers several times a day to assess pain for usual clinical practice and clinical research, at rest and during nociceptive procedures. Further studies are needed to measure the clinical impact of the use of this instrument upon improvements in pain management.

**Acknowledgments** The authors are grateful for the enthusiastic support of the nurses and assistant nurses of the ICU (SAR B) at Saint Eloi Montpellier University Hospital. The authors are also grateful to Patrick McSweeney for his English editing.

**Conflict of interest statement** The authors declare that they have no conflict of interest nor financial supports to disclose.

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## REVIEW PAPER

# Pain assessment tools for unconscious or sedated intensive care patients: a systematic review

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Accepted for publication 12 December 2008

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PUDAS-TÄHKÄ S.-M., AXELIN A., AANTAA R., LUND V. & SALANTERÄ S. (2009) Pain assessment tools for unconscious or sedated intensive care patients: a systematic review. *Journal of Advanced Nursing* 65(5), 946–956.  
doi: 10.1111/j.1365-2648.2008.04947.x

## Abstract

**Title.** Pain assessment tools for unconscious or sedated intensive care patients: a systematic review.

**Aim.** This paper is a report of a systematic review describing instruments developed for pain assessment in unconscious or sedated intensive care patients.

**Background.** Intensive care patients who are unconscious or sedated are unable to communicate and therefore recognition and assessment of the pain is difficult. To assess these patients' pain, it is important to use a valid and reliable pain assessment tool.

**Data sources.** A systematic bibliographical review was conducted, based on seven databases, covering the period from January 1987 to February 2007. A total of 1,586 abstracts was identified and reviewed, 58 papers were selected for full-text review and nine papers were included in the review.

**Methods.** Two researchers independently reviewed the abstracts and three reviewers extracted the papers. The included papers were evaluated using a quality assessment instrument previously developed to evaluate pain assessment tools.

**Results.** Five different pain assessment tools were identified that had been used with unconscious or sedated intensive care patients. All five instruments included behavioural indicators and three included physiological indicators. Their psychometric properties varied and it was not possible to deduce their clinical utility.

**Conclusion.** All instruments were reasonably new. In most of them psychometric testing was in an early stage or even absent. Before any of the reported instruments can be chosen in preference to others, it is essential to test their validity, reliability and feasibility further.

**Keywords:** assessment, intensive care, nursing, pain, sedated, systematic review, unconscious

## Introduction

Most patients receiving intensive care experience unpleasant, frightening and painful events. These patients also frequently

undergo minor or major procedures, many of which are painful and are performed both by nurses and doctors. Mechanical ventilation and airway suctioning can be particularly stressful. Positioning, bed rest, wounds, drains and cannulae all cause

pain to patients. Unrelieved pain causes discomfort to patients, resulting in inadequate sleep, disorientation, exhaustion (Jacobi *et al.* 2002) and possible physiological consequences (Sessler *et al.* 2008). Several researches have showed that pain management in critically ill patients is inadequate (Puntillo 1994, Desbiens *et al.* 1996, Ferguson *et al.* 1997, Carroll *et al.* 1999) and that its severity is often underestimated (Ferguson *et al.* 1997, Carroll *et al.* 1999, Ahlers *et al.* 2008).

Critically ill patients are often unable to communicate because of illness or sedation, in which case recognition and assessment of their pain is difficult. However, pain recognition and assessment are the first steps to effective pain management. Systematic assessment of pain may have an impact on patient outcomes by reducing the duration of mechanical ventilation and rate of nosocomial infections (Chanques *et al.* 2006). The study by Payen *et al.* (2007) showed positive effects on pain management when systematic pain assessment was used.

The American Society for Pain Management Nursing has published recommendations for pain assessment in intubated or unconscious people; these include: a self-report, if possible; potential causes of pain; observation of patient behaviour; surrogate reporting of pain; and use analgesics (Herr *et al.* 2006). A physiological approach to pain assessment has also been described (Jacobi *et al.* 2002, Walco *et al.* 2005).

In uncommunicative patients, pain must be assessed using objective methods based on behavioural and physiological indicators (Puntillo 1990, Kaiser 1992, Hamill-Ruth & Marohn 1999, Kwekkeboom & Herr 2001, Jacobi *et al.* 2002, Herr *et al.* 2006). Facial expressions, such as grimacing, frowning, wrinkling of the forehead and tears, are potential indicators of pain (Rawal & Tandon 1985, Prkachin 1992, Puntillo *et al.* 1997, Kwekkeboom & Herr 2001, Payen *et al.* 2001, Warren Stomberg *et al.* 2001). Patients' movements, especially during procedures, are related to pain, but do not necessarily indicate a conscious pain experience (Puntillo 1990, Payen *et al.* 2001). Immobility can also be a cue that pain is present (Puntillo *et al.* 1997).

Autonomic nervous system-mediated physiological signs, e.g. increased heart rate and blood pressure, may act as cues about pain and thus can be used in the pain evaluation process. The use of physiological signs as the only indicator of pain should be regarded critically. Although these indicators may change in the presence of pain, many other factors influence these changes, such as the patient's illness and medications. Physiological signs also have a tendency to adapt to the presence or absence of pain (Melzack & Katz 1994, Hamill-Ruth & Marohn 1999). As each patient's reactions to pain are unique in intensity and duration, no reliable limits for physiological responses to pain can be set.

Li *et al.* (2008) identified six objective pain tools for use with non-verbal critical care patients. However, two of these included patients' self-reports and therefore they are not suitable for unconscious or sedated patients who cannot communicate verbally.

A good pain assessment tool for unconscious or sedated patients should be feasible, with well-defined instructions and scoring, short, valid, be able to differentiate between pain and no pain, and be sensitive to changes (Jensen *et al.* 1986, Hamill-Ruth & Marohn 1999, Streiner & Norman 2003).

## The review

### Aim

The aim of the review was to describe instruments developed for pain assessment in unconscious or sedated intensive care patients.

The main research questions addressed were:

- Which pain assessment tools have been developed to assess pain of unconscious or sedated intensive care patients?
- What kind of physiological and behavioural indicators these tools include?
- What kind of psychometric properties these tools include?

### Design

We drew on systematic review methods reported in the current systematic review literature (Glasziou *et al.* 2001, Hawker *et al.* 2002) and described by the Centre for Reviews and Dissemination (2001).

### Search methods

A systematic literature search was undertaken from January 1987 to February 2007. The sources searched are in Figure 1. The searches were carried out by a reviewer (SMPT) with the collaboration of a librarian. The keywords used were: pain, assess\$, measure\$, tool, instrument, intensive care, critical care, unconscious, sedation and adult. They were combined with pain and adult and scale or assess\$ or measure\$ or tool or instrument and intensive care or critical care or unconscious or sedation.

### Inclusion criteria

To be included, publications had to:

- describe a pain assessment tool or scale for adult intensive care patients who are unconscious or sedated
- be in English or Finnish.

Database	Records
EBM reviews - Cochrane database of systematic reviews (CDSR)	113
EBM reviews - ACP journal club	2
EBM reviews - Database of abstracts of reviews of effects (DARE)*\$	10
EBM reviews - Cochrane central register of controlled trials (CCTR)\$	200
CINAHL - Cumulative index to nursing & allied health literature	110
Ovid medline (R) in-process & other non-indexed citations	2
Ovid medline (R)	1149
* limit to the period 1987-2007 not valid	
\$ limit to English not valid	

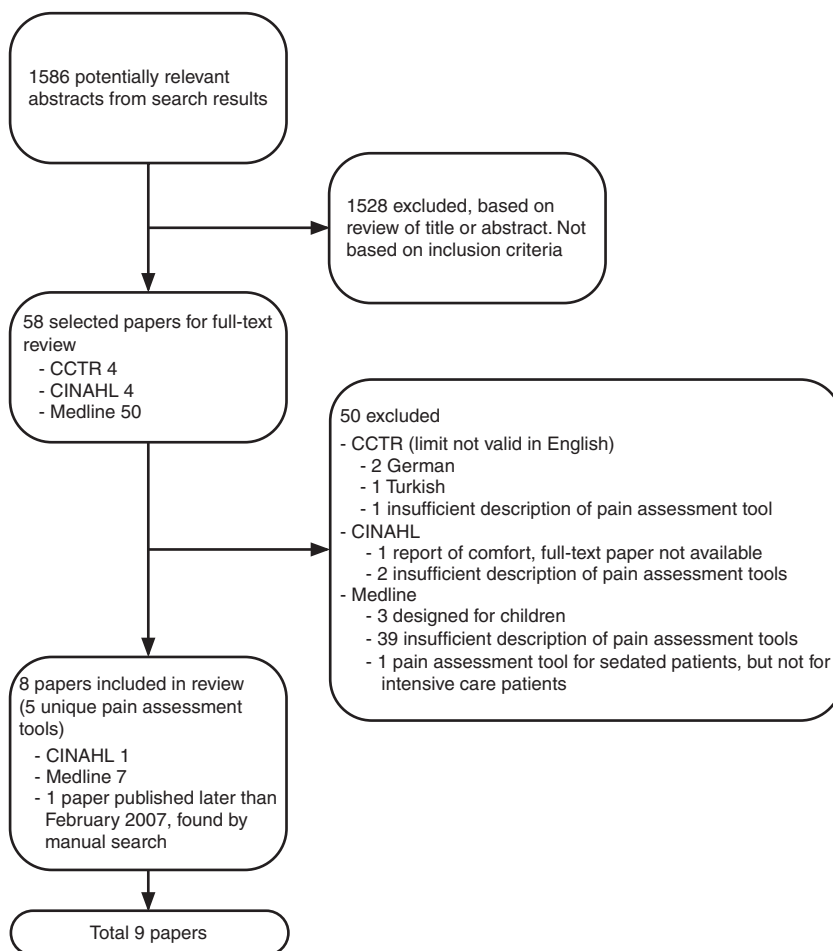
**Figure 1** Sources searched (from 1987 to February 2007) and search results.

### Search outcome

The search strategy yielded 1586 papers, which were reviewed by two reviewers (SMPT, AA) based on the inclusion criteria described above. The process of selection is presented in Figure 2. We selected 58 papers for further analysis. During subsequent consensus discussions, eight papers were chosen for the final analysis, and one was published later than February 2007 was also included, giving a total of nine papers for review. These reports involved five different pain assessment tools.

### Quality appraisal

The papers were independently extracted by three reviewers (SMPT, AA, SS). The criteria used to evaluate the pain assessment tools were based on the instrument reported by Zwakhalen *et al.* (2006). This was developed to evaluate behavioural pain assessment tools for older people with severe dementia. Permission to use the instrument was received from the authors. The instrument focuses on the origin of items, number of participants, content validity, criterion validity, construct validity in relation to other pain



**Figure 2** Process of selection.

tools, construct validity in terms of differentiation, homogeneity, inter-rater reliability, intra-rater and/or test-retest reliability and feasibility. Every item received points from 0 to 2, with a total range of 0–20 (the higher the score, the better quality the tool).

As there is no gold standard for this kind of tool, assessment of content validity was based on the work of Jacobi *et al.* (2002). Each tool received 2 points if it contained both behavioural and physiological indicators, 1 point, if it contained only behavioural indicators and 0 points if it did not cover either of these indicators of content validity.

## Results

The inclusion criteria were met by nine papers, representing five pain assessment tools. Table 1 presents the reviewer-allotted quality scores for the tools.

### Pain assessment tools for unconscious and sedated intensive care unit patients

#### *Behavioral Pain Scale*

The Behavioral Pain Scale (BPS) by Payen *et al.* (2001) was designed for critically ill patients. It consists of facial expressions, movements of the upper limbs and compliance with ventilation. Every item has four descriptions. Each pain indicator has a score from 1 (no response) to 4 (full response).

Payen *et al.* (2001) piloted the BPS tool with 30 surgical patients who were having mechanical ventilation and needed sedation and analgesia. The study was conducted in a trauma and postoperative intensive care unit (ICU). Young *et al.* (2005) carried out research using the BPS tool with 44 mechanically-ventilated patients who were unconscious in a medical, surgical, neurological or emergency ICU. Aissaoui *et al.* (2005) validated the BPS tool further with 30 sedated mechanically-ventilated patients in one ICU.

Criterion validity was tested for the BPS tool. The instrument correlated with changes in physiological indicators in the study by Payen *et al.* (2001), and the latter can be retained as the silver standard (see Table 1). Neither Young *et al.* (2005) nor Aissaoui *et al.* (2005) reported a statistically significant correlation between BPS scores and the physiological indicators. The discriminant validity of this tool was higher during positioning than at rest.

In terms of validation homogeneity, Cronbach's alpha values were satisfactory according to Aissaoui *et al.* (2005) and moderate according to Young *et al.* (2005). Inter-rater agreement was as very good and within an error margin of one point by Payen *et al.* (2001). High inter-rater reliability was also shown in the study of Aissaoui *et al.* (2005). The

results of Young *et al.* (2005) indicated good inter-rater reliability when pain level was low, but when pain level increased, e.g. when assessing patients during turning, inter-rater reliability ranged from 36% to 46%.

We gave the BPS a score of 12/20 for its psychometric properties, which was the highest quality score in the present review.

#### *Critical-Care Pain Observation tool*

The Critical-Care Pain Observation tool (CPOT) by Gélinas *et al.* (2006) was developed for pain assessment in critical care patients and is available in French and English. The instrument has four sections with different behavioural categories: facial expression, body movements, muscle tension, and compliance with the ventilator for intubated patients or vocalization for extubated patients. Items in each category are scored 0–2. Content validity of the tool was evaluated by four physicians and 13 critical care nurses. The content validity indices were 0.88–1.00 for all indicators in the CPOT.

Gélinas *et al.* (2006) carried out a pilot study with 105 patients who had undergone cardiac surgery. There were 33 intubated patients who were unconscious and 99 who were conscious. In another study, Gélinas and Johnston (2007) validated an English version of the CPOT tool with 55 intensive care patients in an ICU, 30 of whom were conscious and 25 of whom were unconscious.

The golden standard in Gélinas *et al.*'s (2006) research was patient self-report of pain. The study showed that this pain intensity correlated moderately with CPOT scores. The other study (Gélinas & Johnston 2007) showed a high Pearson correlation coefficient of 0.71 ( $P \leq 0.05$ ) between a patient's self-report and CPOT scores during turning. No statistically significant correlation was found between a patient's self-report and the physiological indicators.

In the pilot study with the CPOT, the sample size for inter-rater reliability testing fluctuated in every measurement and the weighted  $k$ -coefficients were moderate to high in all assessments (Gélinas *et al.* 2006). The instrument showed high intraclass correlations in all assessments (Gélinas & Johnston 2007), while its discriminant validity was higher during positioning than at rest.

We gave the CPOT a score of 11/20 for its psychometric properties.

#### *Nonverbal Adult Pain Assessment Scale*

The Nonverbal Adult Pain Assessment Scale (NVPS) by Odhner *et al.* (2003) is a pain assessment tool developed for intubated and sedated patients in a burn trauma unit. It was



Table 1 Scores for pain assessment tools

Assessment tool/source	Behavioral Pain Scale (BPS) (Payen <i>et al.</i> 2001)	Critical-Care Pain Observation Tool (CPOOT) (Gélinas <i>et al.</i> 2006)	Nonverbal Adult Pain Assessment Scale (NVPS) (Odhner <i>et al.</i> 2003)	Pain Assessment and Intervention Notation Algorithm (P.A.I.N) (Puntillo <i>et al.</i> 1997)	Pain Assessment Algorithm (Blenkharn <i>et al.</i> 2002)
Dimensions/scoring range	3 behavioural indicators Scale: 3–12	4 behavioural indicators Scale: 0–8	3 behavioural, 2 physiological indicators Scale: 0–10	3-step process: 12 behavioural and 5 physiological Indicators of pain, evaluate the clinical status of the patient and make a pain treatment decision Scale: yes or no	Pain flow chart Scale: 0–3
Origin of items	2	2	1	2	2
2: specially collected for use in intensive care patients with sedation or unconscious	Developed specially for sedated and unconscious ICU patients	Developed specially for sedated and unconscious ICU patients	Modified form an infant pain measure	Developed specially for ICU patients with limited communication	Developed specially for noncommunicative ICU patients
1: items were modified					
0: items originated for another population					
Number of participants	2	2	1	0	0
2: N > 100	3 studies, 104 nonverbal ICU patients	2 studies, 160 ICU patients (129 verbal, 58 nonverbal)	A single study, 59 nonverbal ICU patients	A single study, 31 ICU and PACU patients	Not tested
1: 50 < N < 100					
0: N < 50					
Feasibility	1	1	1	2	0
2: scale is short, manageable, and includes instructions and scoring interpretation	The tool is manageable, not instructions	The tool is manageable, not instructions	The tool is manageable, not instructions	The multifaceted tool	
1: scale is manageable (one format)					
0: scale is more complex					
Content validity	1	1	2	2	2
2: the scale seems to cover all important items or dimensions	Behavioural indicators	Behavioural indicators	Behavioural and physiological indicators	Behavioural and physiological indicators	Behavioural and physiological indicators
1: seems to cover important items or dimensions to a moderate extent					
0: does not seem to cover important items or dimensions					
Criterion validity	1	1	2	0	0
2: correlates high ( $r > 0.60$ ) according to the gold standard	Silver standard: physiological indicators	Gold standard: patients self-report	Gold standard: FLACC – instrument		
1: correlates moderate-acceptable ( $r > 0.40 < 0.60$ )					
0: correlates low ( $r < 0.40$ ), or no information					

Table 1 (Continued)

Assessment tool/source	Behavioral Pain Scale (BPS) (Payen <i>et al.</i> 2001)	Critical-Care Pain Observation Tool (CPOT) (Gélinas <i>et al.</i> 2006)	Nonverbal Adult Pain Assessment Scale (NVPS) (Odner <i>et al.</i> 2003)	Pain Assessment and Intervention Notation Algorithm (P.A.I.N) (Puntillo <i>et al.</i> 1997)	Pain Assessment Algorithm (Blenkham <i>et al.</i> 2002)
Construct validity in relation to other pain tool	0	0	2	0	0
2: correlates are high ( $r > 0.60$ )			NVPS vs. FLACC correlates high (0.86)		
1: correlations are moderate ( $r > 0.40 < 0.60$ )					
0: correlations are low ( $r < 0.40$ ), or no information					
Construct validity II differentiation	2	2	0	0	0
2: differentiates well between pain and no pain	Discriminant validity high during positioning vs. rest	Discriminant validity high during positioning vs. rest			
1: differentiates moderately well					
0: does not differentiate or no information					
Homogeneity	1	0	2	0	0
2: $0.70 < \alpha < 0.90$	0.64–0.72		0.78		
1: $\alpha > 0.90$ or $> 0.60$					
$\alpha < 0.70$					
0: $\alpha < 0.60$ or no information					
Inter-rater reliability	2	2	0	0	0
2: reliability coefficient $> 0.80$	0.82–0.94	0.52–0.88			
1: $0.60 < \text{reliability coefficient} < 0.80$	ICC 0.95	ICC 0.80–0.93			
0: reliability coefficient $< 0.60$ or no information					
Intra-rater and/or test-retest reliability	0	0	0	0	0
2: reliability coefficient $> 0.80$					
1: $0.60 < \text{reliability coefficient} < 0.80$					
0: reliability coefficient $< 0.60$ or no information					
Overall judgement (range 0–20)	12	11	11	6	4



developed on the basis of the FLACC (Face, Legs, Activity, Cry, Consolability) pain assessment tool (Merkel *et al.* 1997), which was constructed for children. The NVPS tool consists of the following categories: face, activity (movement), guarding, physiological signs I (vital signs: systolic blood pressure, heart rate and respiratory rate) and physiological signs II (skin, pupillary response, perspiration, flushing, diaphoretic and pallor). Nursing and medical experts in critical care established the content validity of the instrument components. The pilot study for the NVPS was carried out in a burn trauma unit.

In the study by Odhner *et al.* (2003), the FLACC tool correlated well with the NVPS, the former being considered the gold standard in pain assessment. The construct validity in relation to other pain tools was tested with FLACC. Homogeneity was measured. The alpha coefficient was satisfactory and, when combined with the FLACC, the alpha coefficient was very good.

We gave the NVPS a score of 11/20 for its psychometric properties.

#### *Pain Assessment and Intervention Notation algorithm*

The Pain Assessment and Intervention Notation algorithm (P.A.I.N.) developed by Puntillo *et al.* (1997) has 12 behavioural and eight physiological indicators of pain and was designed especially for intensive care patients. The behavioural indicators are movements, facial indicators and posturing or guarding, and the physiological indicators were heart rate, blood pressure, respiratory rate, perspiration and pallor. A panel of experts in critical care practice and pain established the content validity of the algorithm after multiple reviews until to achieve consensus. There are three steps in the P.A.I.N. Step 1 assesses pain, step 2 assesses process and step 3 involves the analgesic treatment decision.

The P.A.I.N. tool has been tested in three ICUs and in two postanaesthesia care units in two hospitals. The patients had difficulty with verbal communication, but were not unconscious or sedated, and were able to use a numeric rating scale to assess their pain intensity.

We gave the P.A.I.N. tool a score of 6/20. The main reason for low score was lack of reliability testing.

#### *Pain Assessment Algorithm*

The Pain Assessment Algorithm by Blenkarn *et al.* (2002) was designed for non-communicative intensive care patients for the authors' own unit. Its contents are: tachycardia, hypertension, sweating, hypertension with pupil dilation and/or facial grimacing, writhing or distressed movements. The Pain Assessment Algorithm has not yet been clinically tested.

The Pain Assessment Algorithm received a score of only 4/20 in the present reviews because of the lack validity and reliability testing.

## **Discussion**

This systematic review revealed five tools available for unconscious or sedated adult intensive care patients. The psychometric properties of the instruments were evaluated based on quality judgment criteria relating to validity and reliability. The BPS tool received the best scores (12 points out of a maximum 20), and the CPOT and NVPS the next best (11/20 points). The low scores showed that all instruments need further testing and confirmation of various aspects of their psychometric properties.

Earlier, Li *et al.* (2008) reviewed six objective pain measurement tools for use with critical care patients, but their review was not systematic. Their review included The Behavioural Pain Rating Scale (Mateo & Krenzischek 1992) and the Pain Behavior Assessment Tool (Puntillo *et al.* 2004). These tools require that patient is able to communicate verbally, which is not possible for those who are unconscious or sedated. We excluded these two instruments because they were not designed for or tested with patients who were unconscious or sedated. The Pain Assessment Algorithm was excluded from the Li *et al.* (2008) review because it had not been tested. Despite this weakness, we included it in our systematic review as it was designed for unconscious or sedated patients. Li *et al.* (2008) reviewed also the BPS, CPOT, NVPS and P.A.I.N tool. Our results confirmed their findings. Li *et al.* (2008) criticized the NVPS tool because of its weak content validity and reliability. This shows that even the best tools are still under development. However, in our study the NVPS received the second best scores, together with the CPOT tool. The NVPS was the only instrument that received two points for criterion validity, homogeneity and construct validity.

Behavioural parameters are proven, valid signs of pain (Rawal & Tandon 1985, Prkachin 1992, Puntillo *et al.* 1997). In addition, a behavioural response to pain does not necessarily depend on level of consciousness (Payen *et al.* 2001, Gélinas *et al.* 2006). However, sedation may interfere with interpretation of behavioural response to pain (Gélinas & Johnston 2007). Based on these facts, we expected that behavioural parameters would have been included in all pain assessment tools. In two one-dimensional tools, the BPS and CPOT, the entire pain evaluation is based on behavioural signs. Facial expression and body movements are observed with every tool but the definition of these signs varies. The BPS and CPOT focus on changes resulting from growing pain intensity in these two parameters. The NVPS uses body movements in a similar

way to the BPS and CPOT, but for facial expressions it relies on the duration of expressions showing pain during the full measurement period (e.g. occasional grimace or frequent grimace when pain is more intensive). The Pain Assessment Algorithm is built on the assumption that behavioural parameters become evident only during moderate and severe pain. The P.A.I.N. does not objectively rank these behaviours, as it requires checking for the presence of particular signs and then rating pain severity subjectively on a scale from 0 to 10. Other behavioural signs in the P.A.I.N. are guarding, and compliance with the ventilator. All signs can be observed in intensive care patients, but the lack of specific descriptions for the expressions and movements makes assessment subjective.

Physiological signs in relation to pain show somewhat problematic patterns. The health situation in critical care patients is unstable and they need various drugs and treatments, which can have effects on the physiological signs. There is some evidence that heart rate and blood pressure react to pain (Payen *et al.* 2001, Gélinas & Johnston 2007) and correlate with behavioural signs during pain (Puntillo *et al.* 1997). The NVPS, P.A.I.N. and Pain Assessment Algorithm include the physiological parameters of heart rate and blood pressure as indicators of pain. With the NVPS and Pain Assessment Algorithm it is expected that these parameters will increase, and the NVPS sets limit values for this increase. With the P.A.I.N., the changes in both directions are noticed. This solution has advantages, for example in situations such as suctioning, where heart rate can decrease as a consequence of vagal response.

The P.A.I.N. and NVPS also measure change in respiration rate. Other physiological signs used are skin temperature, sweating, dilated pupils, perspiration, flushing, pallor and sweating. However, these signs were not standardized in these tools. Physiological signs remain problematic, as they are not exclusively specific to pain. In addition, it is difficult to set exact limits or the direction of change in these variables. In the future, we need to gather more detailed knowledge of how these signs behave in the context of pain to allow their use for more precise pain indication.

Most pain assessment tools developed for unconscious intensive care patients require no knowledge of specific health conditions when the pain assessment is performed. The P.A.I.N. breaks this notable pattern as the intervention part of this tool includes the assessment of sedation level (Puntillo *et al.* 2002). In pain assessment of neonates who are also incapable of self-report, health condition variables are considered important modifiers of pain manifestation. For example, variables such as behavioural state and gestational age accounted for modifying the pain scores given (Stevens *et al.* 1996). Levels of sedation and unconsciousness also have

an effect on pain manifestation (Gélinas & Johnston 2007) and therefore should be observed systematically when assessing pain.

Evidence of feasibility of the tools was scarce, and criteria for scoring was lacking in almost all reviewed instruments. It was concluded that the P.A.I.N. tool was the only feasible one on the basis of the information given in the papers. We concluded that this is the most feasible of all the instruments evaluated, because of its diversity in the designation of behavioural and physiological indicators of pain. It was also the only tool that included sedation level. There was not enough information about the other instruments to assess their feasibility or clinical utility.

In all studies, the number of patients observed was low. Also some instruments were not especially tested with a focus on unconscious or sedated intensive care patients. One weakness of the studies was that all patients did not represent a typical intensive care patient group, but rather were relatively healthy e.g. cardiac surgery patients. Thus, it would not be appropriate to state that the tools are suitable for the sicker intensive care patients.

The instruments were tested during a painful procedure, e.g. endotracheal suctioning (Payen *et al.* 2001, Odhner *et al.* 2003, Aissaoui *et al.* 2005), positioning (Odhner *et al.* 2003, Young *et al.* 2005, Gélinas *et al.* 2006, Gélinas & Johnston 2007) and venous cannulation (Aissaoui *et al.* 2005). These nociceptive procedures were compared with non-nociceptive procedures, e.g. compression stocking application and central venous catheter dressing change (Payen *et al.* 2001), eye care (Young *et al.* 2005), rest (Odhner *et al.* 2003, Aissaoui *et al.* 2005, Gélinas *et al.* 2006) and non-invasive blood pressure measurement (Gélinas & Johnston 2007). However, it is difficult to determine whether the patient was in pain at rest. There are no published data concerning the incidence of pain at rest in intensive care patients (Chanques *et al.* 2006). Aissaoui *et al.* (2005) stated that at rest the BPS score should be 3, indicating absence of pain, but the scores in their study were close to 4. There are many sources of pain for intensive care patients. The issue of assessing acute, prolonged pain of an intensive care patient who is unconscious or sedated needs more research.

Pain assessment is very challenging in an intensive care environment and should be assessed according to the level of sedation. It is difficult to distinguish pain, from agitation and sedation. There are many confounding factors that interact with these, and the concepts require further research. A comprehensive approach to pain assessment is recommended in non-communicative intensive care patients (Herr *et al.* 2006, Payen *et al.* 2007). The instruments for pain assessment with these patients are still under construction and need more testing of their psychometric properties and clinical utility.

### What is already known about this topic

- Pain in critically ill patients is often underestimated and their pain management inadequate.
- Pain in unconscious or sedated intensive care patients must be assessed using objective methods based on behavioural and physiological indicators.
- There is no gold standard for pain assessment in unconscious or sedated intensive care patients.

### What this paper adds

- Five pain assessment tools developed for unconscious or sedated intensive care patients were identified.
- All instruments are new and have not been widely tested.
- The Behavioral Pain Scale, Critical-Care Pain Observation Tool and Nonverbal Adult Pain Assessment Scale received the best scores in the quality assessment.

### Implications for practice and/or policy

- It is essential to test further the validity, reliability and feasibility of the pain assessment instruments before using them in clinical practice.
- It is advisable to use an instrument to assess pain in clinical practice, since at present undetected pain is not treated individually or effectively.

### Review limitations

There are limitations of our systematic review that need to be addressed. As in any systematic review, it is possible that we failed to identify some papers dealing with the topic. However, we searched multiple databases and collaborated with a librarian to try to that the search was extensive. We did not use unpublished literature, but is possible that this 'grey' literature, e.g. conference proceedings, includes some instruments. Because our search was limited to English and Finnish language journals, we could not capture pain assessment instruments described in other languages. A noteworthy point is that there no gold standard has been established for pain assessment in patients who are unable to give self-reports.

### Conclusion

The psychometric properties of the instruments included in this review varied and evidence of their reliability was lacking. It was also not possible to deduce their clinical

utility. Before any of these instruments can be regarded as the gold standard, it is essential to further test their validity, reliability and feasibility. Although more research is needed, it is advisable to use an instrument to assess pain in clinical practise, since undetected pain cannot be treated either individually or effectively. Systematic pain assessment improves the whole pain care process by making it individual to the patient and by evaluating the effectiveness of pain management.

### Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

### Conflict of interest

No conflict of interest has been declared by the authors.

### Author contributions

SMPT and SS were responsible for the study conception and design. SMPT and AA performed the data collection. SMPT, AA and SS performed the data analysis. SMPT, AA and SS were responsible for the drafting of the manuscript. RA, VL and SS made critical revisions to the paper for important intellectual content. VL and SS supervised the study.

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# Clinical tools for the assessment of pain in sedated critically ill adults

Clare H Cade

## ABSTRACT

**Aim:** This paper aims to review the evidence regarding pain assessment tools for sedated patients and to establish whether the use of a tool can be recommended in practice.

**Background:** Pain assessment is a challenging area of critical care nursing practice, particularly among sedated patients. Tools to aid in assessing pain among this patient group have been developed and tested recently.

**Search strategy:** In this systematic review five papers that tested pain assessment tools for sedated patients are discussed. These papers were identified via the CINAHL and MEDLINE databases using the search terms: 'pain assessment' and 'sedated' or 'unconscious' or 'critically ill' or 'critical illness' or 'critical care'.

**Conclusions:** The Behavioural Pain Scale (BPS) has been tested among the broadest range of patients and was found to be a reliable and valid tool in three studies. Research is needed to further demonstrate the reliability and validity of the Critical-Care Pain Observation Tool (CPOT), as the paper of Gelinas *et al.* did not test its internal consistency and domain structure. The CPOT also needs testing among different critical care populations. The design of Odhner *et al.* study did not allow adequate testing of the Non-verbal Pain Scale (NVPS).

**Implications for practice:** The implementation of the BPS can be recommended in intensive care units and may improve the management of pain among sedated patients by providing a systematic and consistent approach to pain assessment to guide interventions. The CPOT may also prove useful in assessing pain among sedated patients, but first requires further validation. Also, further research is needed into the effects of pain assessment tools on pain management practices and patient outcomes.

**Key words:** Adult intensive care • Pain assessment • Sedation

## INTRODUCTION

The appropriate management of pain has long been a problematic area of nursing research and practice. It is a particularly complex area in the intensive care unit (ICU), where many patients are unable to verbalize their pain. In the following paper, issues relating to pain assessment and management in the ICU are discussed with reference to recent research findings in this field. Five research studies that test pain assessment tools for sedated and unconscious patients are identified and examined, and their implications for future nursing practice are discussed.

## AIM

This paper aims to examine the research evidence to ascertain whether there is a reliable and valid pain assessment tool that could improve the management of pain in sedated and unconscious patients in the ICU.

## BACKGROUND

The management of pain is an important aspect of patient care in the ICU. Many papers indicate that critically ill patients are prone to experiencing pain both by virtue of their pathophysiology (Blakely and Page, 2001), and also as a result of the therapies and procedures that they are subjected to (Summer and Puntillo, 2001; Gacouin *et al.*, 2004). Exposure to high levels of pain has negative psychological and physiological consequences (Blakely and Page, 2001; Summer and Puntillo, 2001), and its effective management is important in the maintenance of patients' dignity (Herr *et al.*, 2006).

The appropriate management of pain depends upon the systematic and accurate assessment of pain to guide decision-making in the titration of analgesia and the administration of 'as needed' medications (Kwekkeboom and Herr, 2001; Stenger *et al.*, 2001; Jacobi *et al.* 2002). It is widely recognized that the patient's own assessment of their pain (using a pain tool) should guide pain management interventions (Kwekkeboom and Herr, 2001) as studies have shown that nurses' estimates of patients' pain levels often understate actual levels (Puntillo *et al.*, 1997; Hall-Lord *et al.*, 1998; Labus *et al.*, 2003). However, many sedated and intubated patients are unable to communicate

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their pain levels, either verbally or by pointing at visual pain scales, making pain assessment particularly difficult in this patient group (Kwekkeboom and Herr, 2001; Stenger *et al.*, 2001; Jacobi *et al.* 2002; Aslan *et al.*, 2003). Other strategies are required to assess pain in these patients.

Puntillo *et al.* (1997) provided some evidence to suggest that physiological indicators (increases in heart rate and blood pressure) can correlate with high levels of pain. However, these cardiovascular changes can occur for reasons other than pain, especially in the critically ill patient. Overall, there is no strong evidence to support the use of physiological indicators in isolation to identify pain. Herr *et al.* (2006) suggest such physiological indicators should be used only as a prompt to further investigate the possibility of pain.

In a large international, multicentre study, Puntillo *et al.* (2004) investigated the behaviours exhibited by patients experiencing pain and identified a number of behavioural indicators of pain (in conscious patients) that they felt may be useful in identifying pain in unconscious and sedated patients. These included grimacing, rigidity, wincing, shutting of eyes and clenching of fists. These indicators are sometimes used by nurses in forming an assessment of pain (as in the study of Gelinas *et al.*, 2004), but in an inconsistent and fragmented way that does not permit clear comparisons over time.

These behavioural indicators have been used to develop pain assessment tools for use in sedated patients. Pain assessment tools are useful as they allow us to monitor for deterioration and improvements over time, and evaluate and titrate analgesic therapy (Kwekkeboom and Herr, 2001; Stenger *et al.*, 2001; Gelinas *et al.*, 2004; Herr *et al.*, 2006). Rietman Wild (2001) highlights the importance of such tools at the bedside to facilitate consistency in decision-making by

individual professionals and to support the widespread delivery of evidence-based practice.

## SEARCH STRATEGY

A focussed literature search was undertaken. CINAHL and MEDLINE databases were searched using the terms 'pain assessment' and 'sedated' or 'unconscious' or 'critically ill' or 'critical illness' or 'critical care'. The search was limited to papers published since 1997 and yielded 19 papers. All research studies that examined the reliability and validity of pain assessment tools for critically ill sedated adults were included in this literature review (a total of five papers).

A number of papers were excluded as they did not validate pain assessment tools. Other papers were excluded as they did not study adult critically ill sedated patients, and their findings would not have been directly transferable to the ICU.

## THE ASSESSMENT TOOLS

Three pain assessment tools for critically ill, sedated patients were identified in the literature. Each of the tools gives a numerical score at each assessment, which can be documented and compared easily over time. Table 1 shows the patient groups with which each tool has been tested.

### The Behavioural Pain Scale

The Behavioural Pain Scale (BPS) is the earliest and most widely tested pain assessment tool for sedated patients. The BPS was developed by Payen *et al.* (2001) (the full tool is shown in their paper) and built on findings from the study of Puntillo *et al.* (1997). Puntillo *et al.* (1997) highlighted the relationship between certain behavioural indicators and patients' self-reports of pain. Payen *et al.* (2001) used these indicators

**Table 1** Patient populations in each study

Authors	Tool tested	Patient population	Number of patient participants	Total number of assessments using tool
Aissaoui <i>et al.</i> (2005)	BPS	General ICU patients (Morocco)	30	360
Gelinas <i>et al.</i> (2006)	CPOT	Elective cardiac surgery (Canada)	105 (33 sedated patients)*	711 (99 assessments on sedated patients)*
Odhner <i>et al.</i> (2003)	NVPS	Trauma, major abdominal surgery and burns ICU (USA)	59	200
Payen <i>et al.</i> (2001)	BPS	Trauma and postoperative ICU (France)	30	269
Young <i>et al.</i> (2006)	BPS	Medical, surgical, neuro and emergency ICU (Australia)	44	168

BPS, Behavioural Pain Scale; CPOT, Critical Care Pain Observation Tool; NVPS, Non-Verbal Pain Scale; ICU, intensive care unit.

\*Gelinas *et al.* (2006) used the CPOT to assess patients at different stages of consciousness.



together to create the BPS. The domain structure of the BPS was confirmed using principle component factor analysis in Payen *et al.* (2001). There are three component domains: 'facial expression', 'upper limb movement' and 'compliance with ventilation'. Within each domain, the patients' behaviour must be scored from 1 to 4. Each increment from 1 to 4 has a description. Professionals decide within each domain which description best expresses the behaviour exhibited by the patient. For example, in the facial expression domain, patients' behaviour might be described as 'relaxed' (score 1); 'partially tightened, e.g. brow lowering' (score 2); 'fully tightened, e.g. eyelid closing' (score 3); 'grimacing' (score 4). Patients are scored from 1 to 4 on each section giving a total score between 3 (no pain) and 12 (maximum pain). The BPS has been tested by Payen *et al.* (2001), Aissaoui *et al.* (2005) and Young *et al.* (2006).

### The Critical-care Pain Observation Tool

Gelinas *et al.* (2006) designed the Critical-Care Pain Observation Tool (CPOT). The CPOT tool was developed using elements of existing pain assessment tools (including the BPS), and other aspects were derived from the authors' previous work (Gelinas *et al.*, 2004). The CPOT has four domains: 'facial expression', 'body movement', 'muscle tension' and 'compliance with ventilation'. Patients are scored in each section between 0 and 2 giving an overall score of 0 (no pain) to 8 (maximum pain). As on the BPS, descriptions are given to explain the behaviours expected for each increment, enabling consistent scoring within each domain. The tool is shown in the paper of Gelinas *et al.* (2006).

### The Non-Verbal Pain Scale

Odhner *et al.* (2003) developed the Non-Verbal Pain Scale (NVPS) based on a tool designed for children (the face, legs, activity, cry, consolability pain assessment tool: the FLACC tool, Merkel *et al.*, 1997). It is stated that the NVPS domains were adapted from the children's FLACC tool based upon findings in the literature; however, little detail about this supporting evidence is presented in the study of Odhner *et al.* (2003) to validate their choice of components. The NVPS incorporates three behavioural domains and two physiological domains. The behavioural domains are: 'face'; 'activity (movement)' and 'guarding'. The first physiological domain considers vital signs and the second incorporates other physiological indicators including skin colour and temperature, perspiration and papillary changes. Again, specific descriptors are given to enable assessors to rate a patient's pain from 0 to 2 within each domain, giving a total pain score between 0 (no pain) and 10 (maximum). The tool is shown in the paper of Odhner *et al.* (2003).

## LITERATURE REVIEW

Each of the five studies aimed to test the reliability and validity of one of the pain assessment tools described above. In the following section, the methods used to assess reliability and validity are discussed to evaluate the quality of each study, and hence determine the plausibility and implications of their findings for current and future clinical practice.

### Research design

Four of the five studies (all except Odhner *et al.*, 2003) used a prospective quasi-experimental repeated measures approach, where they exerted some control over the independent variable (the level of pain) and observed its effect on the dependent variable (the score on the pain assessment tools). They first assessed patients at rest, then introduced an intervention known to elicit pain and reassessed pain levels. The introduction of painful interventions in these studies adds to the validation of the tool, but would be unethical if pain were imposed upon patients purely for the purposes of research. The approach adopted in these studies is acceptable, as the procedures carried out were part of normal care for these patients and no additional exposure was imposed for the purposes of the studies.

Quasi-experimental design offers

*'a weakened confidence in making causal assertions'*

(LoBiondo-Wood and Haber, 2006, p. 228)

than that provided by true experimental design. However, an experimental design is not feasible in testing these tools as pain is multidimensional and is influenced by numerous variables (Carroll *et al.*, 1999; Duhn and Medves, 2004). It is neither practical nor ethical to control all concurrent influences on pain in research. Quasi-experimental studies are therefore the strongest available evidence in the testing of pain assessment tools for sedated patients, and if conducted well could give convincing evidence to support the use of these tools in clinical practice.

The use of the same patients as the control and intervention groups in these studies ensures the highest possible equivalence between the two groups. Thus, changes that occurred in the dependent variable can more safely be attributed to the independent variable being manipulated and not to differences between the control and intervention group characteristics (Polit *et al.*, 2001).

The non-experimental design of Odhner *et al.* (2003) is much weaker as there is no control over patients' pain levels and so no causal relationship can be established between levels of pain and scores on the

tool. This is a problem as if it is not clear that the tool is measuring what it is intended to measure (pain) then its use in practice as a pain assessment tool cannot be advocated.

### Research sample

Each of the papers describes the patient population of the clinical areas in which the pain assessment tools were tested (Table 1). Except for Odhner *et al.* (2003), each of the papers also details inclusion and exclusion criteria for the patients included in the studies. The studies included male and female adult participants and excluded patients who had spinal injuries or who were receiving neuromuscular blocking agents. This is logical and justified as these patients are unable to express the behavioural indicators of pain that comprise the tools (Adam and Osborne, 2005) but establishes a limitation of all of these tools. None of them can be applied in this group of patients.

Convenience samples were used in all the studies. Other than the inclusion and exclusion criteria, no further information is provided regarding their strategies for patient selection. It is unclear whether *all* patients meeting the inclusion and exclusion criteria during the study period were included.

The BPS has been tested among general ICU patients (Aissaoui *et al.*, 2005; Young *et al.*, 2006), and among trauma and surgical patients (Payen *et al.*, 2001). The other tools have only been tested in a single setting with a specific patient group. CPOT of Gelinac *et al.* (2006) was tested among elective cardiac surgery patients. NVPS of Odhner *et al.* (2003) was tested among burns and trauma patients. All the studies discussed here were tested among sedated and/or unconscious patients. Gelinac *et al.* (2006) additionally used the CPOT to assess patients once awake.

Although the actual numbers of patients included in each study were relatively small, importantly, multiple pain assessments were completed with each patient at different times in each study. The studies therefore refer to the total number of administrations of the tools as their sample size. This is reasonable as each application of each tool adds to the testing of its reliability and validity. The participant numbers are detailed in Table 1.

Although none of the studies discussed how they decided their required sample size, the chosen numbers (between 168 and 360 administrations of the tools) were adequate for the calculation of useful statistics except in the study of Young *et al.* (2006) where inadequate data were gathered for the calculation of inferential statistics for inter-rater reliability (only 11 patients were assessed by more than one evaluator). This limits the strength of the inter-rater reliability

findings (White and van den Broek, 2004). None of the papers detailed power analyses in planning their samples.

### Data collection

It is only possible to recommend the use of an assessment tool if the tool is proven to be valid and reliable. A valid tool

*'measures what it is supposed to be measuring'*

(Polit *et al.*, 2001, p. 308).

Clearly this is important as if the tool is implemented to assess pain and influence decisions regarding analgesia, practitioners need to be sure that it is pain that is being measured. A reliable tool

*'yields the same results on repeated measures'*

(LoBiondo-Wood and Haber, 2006, p. 345).

This too is important in practice as the tool needs to generate consistent results when used by different assessors and at different times, so that comparisons can be made and the effectiveness of interventions assessed.

Different methods were used in the five studies to test the reliability and validity of the tools. The use of a repeated measures design in all except the study of Odhner *et al.* (2003) allowed the contrasting of groups and the testing of construct validity. Construct validity

*'examines whether the abstract concept or construct has in fact been adequately measured'*

(Duhn and Medves, 2004, p. 129).

It was important for all the studies to show that the pain assessment tools were indeed measuring pain. The evaluation of construct validity involves testing relationships on the basis of theoretical considerations (Polit *et al.*, 2001). In this case, by assessing pain both at rest and then during painful interventions, testing the hypothesis that scores on their pain tools would be significantly greater during the painful procedures than at rest (reflecting the anticipated increase in pain). Young *et al.* (2006) and Payen *et al.* (2001) also introduced a non-painful procedure during which no significant increase in pain score was expected. This further tested the BPS's validity, ensuring that increases in the BPS score were only seen when pain was increased and not in response to other factors.

Aissaoui *et al.* (2005) and Young *et al.* (2006) selected the painful procedures for their study based on evidence from previous research (mainly Puntillo

*et al.*, 2001), which showed that endotracheal suctioning, repositioning and line insertions were identified by patients as painful procedures. The researchers do not state how they ascertained that eye care, the application of compression stockings and line-dressing changes were non-painful procedures. In the study of Payen *et al.* (2001), uncertainty over the selection of compression stocking application as a non-painful procedure becomes an issue in interpreting their results (this is discussed later).

Odhner *et al.* (2003) did not test construct validity. Instead, they chose to assess criterion validity. Confirmation of criterion validity requires

*'correlations of the measure with another criterion measure, which is accepted as valid (referred to as the "gold standard")'*

(Bowling, 1997, p. 133)

Such comparisons should tell us how the tool performs when compared with another measure that we know assesses pain accurately. Odhner *et al.* (2003) assessed patients' pain with the FLACC tool as the 'gold standard' as well as their newly developed NVPS to allow comparison and consequently establish the validity of the NVPS against the FLACC as the 'gold standard'. While this seems rational in principle, this process was flawed as the FLACC tool itself has never been validated among adult patients, so cannot logically be regarded as a 'gold standard' accurate pain assessment tool.

Gelinas *et al.* (2006) also assessed criterion validity. They were able to obtain patients' own assessments of pain in addition to the nurses' CPOT assessments, as their patients were being woken and weaned. This allowed the comparison of CPOT scores with patients' own assessments, which might more reasonably be considered the 'gold standard' in pain assessment. This gave some indication that the behaviours accurately reflected actual pain levels in the conscious patients, suggesting that this may also be the case among the sedated patients (for whom we cannot obtain the 'gold standard' self assessment of pain).

The four quasi-experimental studies provided rigorous testing of the construct validity of the BPS and the CPOT. The factor analysis work in Payen *et al.* (2001) adds to this by confirming the domain structure of the BPS. Gelinas *et al.* (2006) testing of criterion validity further strengthened their study design, adding to the testing of the CPOT's validity. The lack of any factor analysis work is a limitation of their research however, which prevents us from drawing confident conclusions about the overall validity of the CPOT, as we do not have confirmation

of the tool's domain structure. The design of Odhner *et al.* (2003) did not allow adequate testing of the validity of the NVPS.

In all the studies, the pain assessments were carried out by more than one professional for at least some of the assessments. This allowed the comparison of scores to show whether different assessors obtained the same scores when using the tool to assess the same patient at the same time. This gives a measure of the reliability of the tools. Good inter-rater reliability gives assurance that when implemented in practice, scoring will be consistent when the tool is used by the many different professionals on the ICU.

## Data analysis

Various statistical tests were used in the five studies to evaluate the reliability and validity of the tools. Key results are summarized in Table 2. Each of the studies that tested the BPS showed that BPS scores were significantly higher during painful procedures than at rest, demonstrating good construct validity. Young *et al.* (2006) additionally showed that BPS scores were not significantly higher during non-painful procedures, further supporting construct validity. Payen *et al.* (2001) found a discrepancy between the two non-painful procedures. They found no significant increase in BPS during central venous catheter dressing changes, but found a significant increase during compression stocking application. The authors identify in their discussion, however, that this is likely to reflect the inappropriate choice of compression stocking application as a non-painful intervention, rather than the construct validity of the tool. This is reasonable as the mobilization of limbs during this procedure may actually have been painful for their trauma and surgical patient participants. Gelinas *et al.* (2006) showed that CPOT scores were also significantly higher during painful procedures than at rest. These studies demonstrated that the BPS and the CPOT both had good construct validity. Odhner *et al.* (2003) did not assess construct validity.

Odhner *et al.*'s (2003) study attempted to evaluate criterion validity by comparing NVPS scores with FLACC tool scores. They calculated a Pearson's correlation of 0.86. A correlation greater than 0.7 shows a strong positive relationship between the two variables (i.e. a strong correlation between the scores on the two tools). The FLACC tool is *not*, however, accepted as valid for adult patients, giving these results little meaning with regard to the validity of the NVPS. Gelinas *et al.* (2006) compared patients' own assessments of pain once they were conscious, and nurses' simultaneous CPOT assessments. They calculated

**Table 2** Key results from the studies

Tool	Authors	Reliability	Validity
BPS	Payen <i>et al.</i> (2001)	Inter-rater reliability <ul style="list-style-type: none"> <li>Weighted <math>\kappa</math> coefficient = 0.74</li> </ul>	Construct validity <ul style="list-style-type: none"> <li>Significantly higher BPS score during painful procedures than during non-painful (means 4.9 and 3.5 respectively) <math>F</math>-test = 49.0, <math>p &gt; 0.01</math> (mean BPS at rest 3.0 and 3.2 respectively)</li> <li>Principal component factor analysis – large first factor accounting for 55% of variance in pain expression</li> </ul>
	Aissaoui <i>et al.</i> (2005)	Inter-rater reliability <ul style="list-style-type: none"> <li>Intraclass correlation coefficient = 0.95</li> </ul> Internal consistency <ul style="list-style-type: none"> <li>Cronbach's <math>\alpha</math> = 0.72</li> </ul>	Construct validity <ul style="list-style-type: none"> <li>BPS scores significantly higher during painful procedures (<math>6.8 \pm 1.9</math>) than at rest (<math>3.9 \pm 1.1</math>), <math>p &lt; 0.001</math></li> </ul>
	Young <i>et al.</i> (2006)	Inter-rater reliability <ul style="list-style-type: none"> <li>Rater agreement<sup>†</sup> <ul style="list-style-type: none"> <li>82–91% pre-procedure</li> <li>64–73% post-non-painful procedure</li> <li>36–46% post-painful procedure</li> </ul> </li> </ul> Internal consistency <ul style="list-style-type: none"> <li>Cronbach's <math>\alpha</math> = 0.64</li> </ul>	Construct validity <ul style="list-style-type: none"> <li>73% of scores higher during painful procedure than at rest (significant <math>p \leq 0.003</math>)</li> <li>14% of scores higher during non-painful procedures (not significant <math>p &gt; 0.3</math>)</li> </ul>
NVPS	Odhner <i>et al.</i> (2003)	Inter-rater reliability <ul style="list-style-type: none"> <li>No data reported in paper</li> </ul> Internal consistency <ul style="list-style-type: none"> <li>Coefficient <math>\alpha</math> = 0.78</li> </ul>	Criterion validity <ul style="list-style-type: none"> <li>Pearson's correlation = 0.86 (between FLACC 'gold standard' scores and NVPS scores) (<math>p &lt; 0.05</math>)</li> </ul>
CPOT	Gelinas <i>et al.</i> (2006)	Inter-rater reliability <ul style="list-style-type: none"> <li>Weighted <math>\kappa</math> coefficient = 0.52–0.88 during different assessment periods</li> </ul>	Criterion validity <ul style="list-style-type: none"> <li>Patients' own assessments compared with CPOT scores (<math>p \leq 0.001</math>)</li> <li>Spearman's correlation (extubated patients) = 0.40–0.59 (patients' own scores moderately correlated with CPOT scores)*</li> </ul> Construct validity <ul style="list-style-type: none"> <li>CPOT scores at rest compared with scores during procedures (<math>p \leq 0.001</math>)</li> <li>Paired <math>t</math>-tests = <math>-9.01</math> to <math>-15.96</math> (CPOT scores significantly higher during positioning than at rest)</li> </ul>

BPS, Behavioural Pain Scale; NVPS, Non-Verbal Pain Scale; CPOT, Critical-Care Observation Tool.

\*Gelinas *et al.* (2006) used the CPOT to assess patients at different stages of consciousness.

†Young *et al.* (2006) had inadequate sample size for calculation of inferential statistics

Spearman's correlation coefficients of 0.40–0.59 indicating moderate agreement.

All the studies assessed the agreement between assessors (inter-rater reliability). Table 3 shows acceptable values for these tests. Payen *et al.* (2001) and Gelinas *et al.* (2006) calculated weighted  $\kappa$  coefficients. A  $\kappa$  coefficient of 0.74 in Payen *et al.* (2001) suggests that the BPS had good inter-rater reliability.  $\kappa$  coefficients between 0.52 and 0.88 in Gelinas *et al.* (2006) suggest that the CPOT had fair to excellent inter-rater reliability during the different assessment periods. Aissaoui *et al.* (2005) calculated an intraclass coefficient of 0.95, which suggests that the BPS also had good inter-rater reliability in this study. Young *et al.* (2006) gave descriptive

statistics only for inter-rater reliability. Agreement was good when BPS scores were low (82–91% pre-procedure and 64–73% during non-painful procedures), but were lower when the BPS scores were high (36–46% during painful procedures). Odhner *et al.* (2003) did not report their data for inter-rater reliability. Payen *et al.* (2001), Gelinas *et al.* (2006) and Aissaoui *et al.* (2005) demonstrated that the BPS and CPOT had adequate inter-rater reliability to make their use in practice feasible.

Measurements of the internal consistency of an instrument determines whether

*'all its sub-parts measure the same characteristic'*

(Polit *et al.*, 2001, p. 366)

**Table 3** Statistical tests for reliability

Aspect of reliability tested	Indications for testing aspect of reliability	Statistical test	Acceptable values
Internal consistency	To assess the homogeneity of the tool (i.e. to establish whether all subparts of the tool are measuring the same attribute)	Cronbach's $\alpha$ (also known as coefficient $\alpha$ )	>0.50 moderate >0.70 good <sup>^</sup>
Inter-rater reliability	Used to show whether the tool yields consistent results when applied by different assessors	$\kappa$ coefficient	<0.40 poor agreement 0.40–0.59 fair agreement 0.60–0.74 good agreement*
		Intraclass correlation coefficient	>0.80 acceptable*

\*Bowling (1997); <sup>^</sup>White and van den Broek (2004).

These calculations should establish whether all domains on the tools relate to pain. Most of the studies calculated a Cronbach's  $\alpha$  or coefficient  $\alpha$  giving values from 0.64 for the BPS in Young *et al.*'s (2006) study to 0.78 for the NVPS in Odhner *et al.*'s (2003) study (Table 2). The nearer the value to 1 the more internally consistent the tool, suggesting moderate internal consistency in the study of Young *et al.* (2006), and good internal consistency in the other studies. All the tools demonstrated acceptable internal consistency except for the CPOT, as Gelinas *et al.* (2006) did not test this aspect. This is a limitation of Gelinas *et al.*'s (2006) study. It does not demonstrate that every domain on the CPOT is measuring pain. The reliability of the CPOT has therefore not been adequately tested by this study.

### Findings

The BPS was found to have good construct validity in all three studies. Significantly higher scores were obtained during painful procedures than at rest, and no significant increase occurred in two of the three non-painful interventions tested. The increase seen in the study of Payen *et al.* (2001) during compression stocking application can be attributed to the likelihood that this was in fact a painful procedure in the participant population. The tool was also found to have acceptable inter-rater reliability. While Young *et al.* (2006) showed poorer agreement at the higher end of the scale, the difference never exceeded two points overall, and the other BPS studies did not show significant divergence between assessors. The BPS was found to be internally consistent, with each domain on the tool found to relate to pain.

The CPOT was shown to have good construct validity and moderate criterion validity. Inter-rater reliability was acceptable. However, validity and reliability were not fully assessed in Gelinas *et al.*'s (2006) study. Internal consistency was not assessed and

no factor analysis work was reported to confirm its domain structure.

The validity of the NVPS was not adequately tested. Construct validity was not tested, and criterion validity was tested against a tool that cannot reasonably be termed the 'gold standard'. Internal consistency was good, but conclusions cannot be drawn regarding inter-rater reliability as the data are not reported for this.

### DISCUSSION

There is strong evidence to support the validity and reliability of the BPS as this tool has been tested in a variety of specialist and general ICU settings and has shown good reliability and validity in three studies (Payen *et al.*, 2001; Aissaoui *et al.*, 2005; Young *et al.*, 2006). Additional haemodynamic data collected from the studies of Young *et al.* (2006) and Payen *et al.* (2001) showed that physiological indicators lacked specificity in identifying pain in patients. This further supports the use of behavioural indicators.

Some issues with the BPS were identified however. Payen *et al.* (2001) express concerns regarding the close relationship between patients' sedation scores and their BPS scores. It is unclear whether lower scores are found in more heavily sedated patients because they experience less pain or because they are simply less able to exhibit the behaviours on the tool. Additionally, Payen *et al.* (2001) and Young *et al.* (2006) identified that their studies had not tested the BPS at the higher extreme of the scale. Young *et al.* (2006) suggest, however, that it would be very difficult to assess these levels practically in research as it would require the manipulation of pre-existing analgesic regimes to expose patients to greater levels of pain, and this would not be ethically sound. Both these issues are difficult to address practically in research but are

important to consider when implementing the BPS in clinical practice.

The findings in Odhner *et al.* (2003) suggest that their NVPS will need considerable further development and subsequent testing before its use can be supported in practice. The use of a non-experimental design and an invalidated 'gold standard' tool, gave no assurance of the validity of this tool.

The CPOT demonstrated good reliability and validity in all aspects that were tested in Gelinas *et al.*'s (2006) study; however, the validation of this tool was not complete. Factor analysis work to confirm its domain structure is needed to further support its construct validity. Additionally, evidence of the tool's internal consistency is needed to ensure that it is a reliable tool before its clinical use can be recommended. Also, the CPOT has only so far been tested among cardiac surgery patients. The CPOT requires validation among broader critical care populations if its wider use is to be advocated in the future.

While these studies demonstrate that the BPS had good reliability and validity, and the CPOT shows promise, they do not give evidence to show how the implementation of these tools impacts upon the management of pain. Chanques *et al.* (2006) have since evaluated the impact of the combined systematic assessment of pain and sedation (using the BPS for pain) in general ICU patients. They found that this was associated with reduced pain and agitation, and reduced duration of mechanical ventilation and nosocomial infections. More titration (escalation and de-escalation) of analgesia occurred in the intervention group. Further testing of the effect of the BPS and CPOT on pain management practices is needed.

Despite the positive findings of these studies, Payen *et al.* (2007) found that many patients in their recent large multicentre study were receiving analgesia without concurrent documentation of pain assessments. They found that many ICUs were not incorporating assessment tools for non-verbal patients (such as those discussed in this paper) into their pain management guidelines and protocols.

## IMPLICATIONS FOR NURSING PRACTICE

Nurses are responsible for the administration of prescribed 'as needed' analgesia, the titration of analgesic drug infusions within prescribed parameters and the implementation of non-pharmacological measures to reduce pain on many ICUs. To perform this role appropriately requires the accurate and consistent assessment of pain. The lack of a systematic and standardized method for evaluating and documenting pain levels prevents the comparison of pain levels over

time and therefore evaluation of the effectiveness of patients' analgesic regimes.

In view of this, the findings of Gelinas *et al.* (2004) and Payen *et al.* (2007) suggest that there is a danger that pain is still not being managed appropriately in sedated patients, as many ICUs still have no consistent or systematic approach towards assessing pain among sedated patients. This practice is not consistent with recommendations in the literature. The systematic assessment of pain using evidence-based tools is advocated (Herr *et al.*, 2006).

This review of the literature suggests that the BPS tool could be applied clinically to measure pain in ICU patients in a systematic and comparable way. The measurement of pain levels in this way could allow nurses and other professionals to identify patients experiencing escalating pain and administer analgesia in such instances to avoid exposing patients to the distressing and potentially physiologically harmful consequences of pain. The regular use of such a tool could also help nurses to recognize when analgesia can be appropriately reduced, helping to ensure the earliest possible weaning and extubation, and perhaps earlier ICU discharge as a consequence (Chanques *et al.*, 2006).

One potential limitation of all these tools surrounds their use among agitated patients. The constituent behavioural indicators of pain in the tool descriptors might also be demonstrated in patients with agitation (Riker *et al.*, 1999), many of whom may not have pain. This should not prevent us from utilizing the tools however, as they would still prompt the consideration of pain as a possible cause of a patients' agitation. When a patient displays agitation, Herr *et al.* (2006) recommend exploration of all possible causes of distress, and the initiation of an analgesic trial to differentiate between pain and agitation of other causes.

None of these tools can be recommended in practice to assess pain in patients with spinal injuries and those receiving neuromuscular blocking agents as these patients' ability to express the behaviours may be impaired. The behavioural tools should also not replace attempts to ascertain patients' own assessments of pain where this is possible. Furthermore, efforts should also be made to anticipate procedural pain and administer pre-emptive analgesia accordingly (Herr *et al.*, 2006).

## CONCLUSION

The tools tested in these studies offer a consistent and systematic approach, which might improve the management of pain on ICUs. The BPS tool particularly has

been shown to have good reliability and validity in a range of ICU patients and could offer an improvement on the current fragmented assessment of pain in sedated patients if incorporated into guidelines and protocols for pain management on ICUs. The CPOT also showed promising results, but the study of Gelinas *et al.* (2006) did not yield sufficient evidence of its reliability and validity to support its use in clinical practice at the current time. Further research that assesses the reliability and validity of the CPOT more thoroughly is required, and studies which test the

tool among other patient populations within critical care. Future research should also further investigate the impact of behavioural pain assessment tools on pain management in clinical practice.

## ACKNOWLEDGEMENTS

The author would like to thank those on the Liver Intensive Therapy Unit at Kings College Hospital NHS Trust who provided support and encouragement during the writing of this paper.

### WHAT IS KNOWN ABOUT THIS TOPIC

- The management of pain among sedated patients is a complex area of ICU research and practice, which relies upon the accurate and consistent assessment of pain.
- Research has suggested that pain should be assessed systematically using a validated tool.

### WHAT THIS PAPER ADDS

- This paper draws together the evidence regarding the validation of tools for the assessment of pain in sedated patients and shows that the BPS is a reliable and valid tool for the assessment of pain in sedated patients which has been tested in a range of ICU settings.
- This paper also proposes further research to validate the CPOT, and further investigation into the impact of behavioural pain assessment tools on pain management practices.

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# VALIDATION OF THE CRITICAL-CARE PAIN OBSERVATION TOOL IN ADULT PATIENTS

By Céline Gélinas, RN, PhD, Lise Fillion, RN, PhD, Kathleen A. Puntillo, RN, DNSc, Chantal Viens, RN, PhD, and Martine Fortier, MPs. From School of Nursing, McGill University, Montreal, Quebec (CG), Faculty of Nursing, Laval University, Quebec City, Quebec (LF, CV, MF), and Department of Physiological Nursing, University of California, San Francisco, Calif (KP).

- **BACKGROUND** Little research has been conducted to validate pain assessment tools in critical care, especially for patients who cannot communicate verbally.
- **OBJECTIVE** To validate the Critical-Care Pain Observation Tool.
- **METHODS** A total of 105 cardiac surgery patients in the intensive care unit, recruited in a cardiology health center in Quebec, Canada, participated in the study. Following surgery, 33 of the 105 were evaluated while unconscious and intubated and 99 while conscious and intubated; all 105 were evaluated after extubation. For each of the 3 testing periods, patients were evaluated by using the Critical-Care Pain Observation Tool at rest, during a nociceptive procedure (positioning), and 20 minutes after the procedure, for a total of 9 assessments. Each patient's self-report of pain was obtained while the patient was conscious and intubated and after extubation.
- **RESULTS** The reliability and validity of the Critical-Care Pain Observation Tool were acceptable. Interrater reliability was supported by moderate to high weighted  $\kappa$  coefficients. For criterion validity, significant associations were found between the patients' self-reports of pain and the scores on the Critical-Care Pain Observation Tool. Discriminant validity was supported by higher scores during positioning (a nociceptive procedure) versus at rest.
- **CONCLUSIONS** The Critical-Care Pain Observation Tool showed that no matter their level of consciousness, critically ill adult patients react to a noxious stimulus by expressing different behaviors that may be associated with pain. Therefore, the tool could be used to assess the effect of various measures for the management of pain. (*American Journal of Critical Care*. 2006;15:420-427)

Pain is an important stressor for many patients in critical care,<sup>1,3</sup> and it is not unusual for the intensity of the pain to be described as moderate to severe.<sup>4-12</sup> Pain assessment is the first step in proper pain relief, an important goal in patients' care. Although critical care clinicians strive to obtain each patient's self-report of pain, many factors compromise patients' ability to communicate verbally, including the use of

sedative agents, mechanical ventilation, and changes in the level of consciousness.<sup>13,14</sup> Several pain scales have been used to document self-reporting of pain in intubated patients.<sup>7-9,12</sup> In the absence of a patient's self-report, observable behavioral and physiological indicators become important indices for the assessment of pain.<sup>13,15-17</sup>

Preliminary research<sup>18-20</sup> has been conducted to validate instruments that include behavioral and/or physiological indicators. Use of these instruments in critical care practice is restricted because of the limitations of the studies. Limitations include small sample sizes (<40 patients),<sup>18-20</sup> lack of validation in intubated

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**Table 1** Description of the Critical-Care Pain Observation Tool

Indicator	Description	Score	
Facial expression	No muscular tension observed	Relaxed, neutral	0
	Presence of frowning, brow lowering, orbit tightening, and levator contraction	Tense	1
	All of the above facial movements plus eyelid tightly closed	Grimacing	2
Body movements	Does not move at all (does not necessarily mean absence of pain)	Absence of movements	0
	Slow, cautious movements, touching or rubbing the pain site, seeking attention through movements	Protection	1
	Pulling tube, attempting to sit up, moving limbs/ thrashing, not following commands, striking at staff, trying to climb out of bed	Restlessness	2
Muscle tension Evaluation by passive flexion and extension of upper extremities	No resistance to passive movements	Relaxed	0
	Resistance to passive movements	Tense, rigid	1
	Strong resistance to passive movements, inability to complete them	Very tense or rigid	2
Compliance with the ventilator (intubated patients)	Alarms not activated, easy ventilation	Tolerating ventilator or movement	0
	Alarms stop spontaneously	Coughing but tolerating	1
	Asynchrony: blocking ventilation, alarms frequently activated	Fighting ventilator	2
OR			
Vocalization (extubated patients)	Talking in normal tone or no sound	Talking in normal tone or no sound	0
	Sighing, moaning	Sighing, moaning	1
	Crying out, sobbing	Crying out, sobbing	2
Total, range			0-8

patients,<sup>18</sup> use of a subjective scale (eg, absence, slight, moderate, and extreme intensity of behaviors),<sup>18</sup> confusion in the definition of behaviors (eg, body movements and muscle rigidity), and use of dependent observations (ie, statistical analysis of the observations rather than of the sample of patients).<sup>19</sup> The aim of our study was to examine the reliability and validity of a newly developed instrument for pain assessment: the Critical-Care Pain Observation Tool (CPOT).

*Behavioral and physiological indicators are important indices for assessment of pain in patients unable to self-report.*

## Method

### Design, Sample, and Ethics

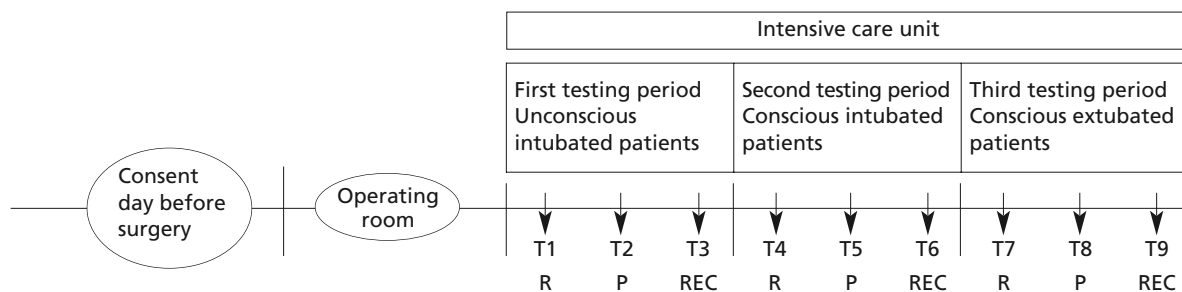
A repeated measures design was chosen for this quantitative study. A convenience sample of 105 cardiac surgery patients in the intensive care unit (ICU) at a cardiology health center in Quebec, Canada, was recruited for the study. Patients were considered for inclusion if

they were 18 years or older, had been admitted for cardiac surgery, understood French, were in the ICU after surgery, and were able to hear and to see. Patients were excluded if they had been admitted for a heart transplant or thoracic aortal aneurysm repair, received medical treatment for chronic pain, had an ejection fraction less than 0.25, had preexisting psychiatric or neurological problems, had a dependence on alcohol or drugs, received neuromuscular blockers following surgery, or had complications after surgery (eg, hemorrhage, delirium, death).

This study was approved by the human research committee of the health center. Recruitment was done the day before the surgery; the study was explained to eligible patients, and informed consent was obtained. At this time, patients were taught how to use the pain intensity descriptive scale.

### Instruments

*Critical-Care Pain Observation Tool.* The CPOT, developed in French, has 4 sections, each with different behavioral categories: facial expression, body movements, muscle tension, and compliance with the ventilator for intubated patients or vocalization for extubated patients (Table 1). Items in each section are



**Figure 1** Illustration of the time of consent and the 3 testing periods.

Abbreviations: P, positioning procedure; R, rest; REC, recovery (20 minutes after the positioning procedure).

scored from 0 to 2, with a possible total score ranging from 0 to 8. The CPOT was developed as follows. Some items and their operational definitions were derived from previously described instruments for pain assessment.<sup>18-21</sup> In addition, pain indicators were described by using findings from a chart review of the medical files of 52 critically ill patients<sup>22</sup> and from 9 focus groups with 48 critical care nurses and interviews of 12 physicians.<sup>23</sup>

Content validity of the CPOT was established with 4 physicians and 13 critical care nurses. The physicians and nurses completed a questionnaire on the relevance of the inclusion of these indicators in the CPOT by using a Likert scale (1 = not at all, 2 = a little, 3 = moderately, and 4 = very much). Content validity indices, which are the proportion of participants who answered 3 or 4 on the Likert scale, were calculated. All indicators had indices of 0.88 to 1.00. Content validity indices greater than 0.80 were sufficiently satisfactory<sup>24</sup> to consider including all these indicators in the CPOT.

**Pain Intensity Descriptive Scale.** A previously validated pain intensity descriptive scale (0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = unbearable) was used. This scale has been used in previous studies<sup>18,25</sup> in acute and critical care.

**Confusion Assessment Method for the Intensive Care Unit.** The Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) was used to assess delirium. The instrument has good sensitivity and specificity for assessing delirium in critically ill patients.<sup>26,27</sup> Two modifications were made in the CAM-ICU to adapt it to the sedation scale used in our study and to facilitate assessment of patients' inattention. First, the Ramsay Scale<sup>28</sup> was used to assess the level of sedation. Second, patients' inattention was verified by assessing their capacity to concentrate on the pain intensity descriptive scale used in our study.

## Procedure

Three testing periods, each including 3 assessments for a total of 9 pain assessments (T1-T9) with the CPOT, were completed during each patient's early postoperative course (Figure 1). For each patient, the first 3 assessments (T1-T3) were done while the patient was intubated and still unconscious (ie, with a sedation score of 5 or 6 on the Ramsay Scale). T1 was done with the patient at rest, approximately 2 hours after the end of surgery. T2 was completed a few minutes after T1 during positioning of the patient. Positioning represented a previously confirmed nociceptive procedure.<sup>9</sup> On the basis of the patient's needs, endotracheal suctioning often was performed at the same time as positioning. Finally, T3 was done at recovery, 20 minutes after the positioning procedure.

The second testing period (assessments T4-T6) was 3 hours after the first testing period. During this time, the patient was still intubated but conscious. Patients were considered conscious if they had a score of 2, 3, or 4 on the Ramsay Scale.

Finally, the third testing period (assessments T7-T9) was after the patient was extubated, approximately 5 hours after the second testing period. The positioning procedure at T8 sometimes occurred with ambulation and/or respiratory exercises, which were part of the postoperative care protocol.

For each of the 3 testing periods, patients were evaluated with the CPOT for 1 minute at rest both before and after positioning and for the duration of the positioning procedure. This standardization of procedures was based on the work of Puntillo et al.<sup>9</sup> One of us (C.G.) and a critical care nurse (G.N.) evaluated the patients. Upon completion of the CPOT during the second testing period (ie, assessments T4-T6), intubated patients communicated the presence or absence of pain by nodding their heads (yes or no) to the

**Table 2** Description of reliability and validity methods examined in this study

Psychometric property	Description	Coefficient or analysis	Level of acceptability*	
Interrater reliability	Interrater reliability is the consistency with which 2 raters agree on their measurement/observation (ie, the CPOT) of a phenomenon (ie, pain) Two raters assessed the patients in this study: the principal investigator and 1 critical care nurse	$\kappa$ coefficient (proportion of responses in which the 2 raters agreed)	<0	Poor
			0-0.20	Slight
			0.21-0.40	Fair
			0.41-0.60	Moderate
			0.61-0.80	Substantial
			0.81-1.00	Almost perfect
Criterion validity	Criterion validity refers to the relationship between the instrument (ie, the CPOT) and the gold standard measure of pain (ie, the patient's self-report) In this study, yes/no and pain intensity were used as the gold standard self-report measures	Intubated patients (T4-T6): analysis of variance	$P \leq .01$	
		Extubated patients (T7-T9): Spearman correlation		
Discriminant validity	Discriminant validity refers to evidence that instruments measuring 2 different constructs should not correlate In this study, we examined whether the CPOT could be used to discriminate between pain during positioning and lack of pain at rest	Rest time compared with positioning for all three testing periods: paired $t$ test	$P \leq .01$	

Abbreviation: CPOT, Critical-Care Pain Observation Tool.

\* Levels of acceptability for interrater reliability scores from Landis and Koch.<sup>30</sup>

question, Do you have pain? This procedure was selected because many intubated patients during this phase of their recovery were unable to use the pain intensity descriptive scale. Before the third testing period, at T7, patients were evaluated by using the CAM-ICU to determine the presence of delirium. Three patients were excluded because of delirium. During the third testing period (ie, assessments T7-T9) after completion of the CPOT, the extubated patients used the pain intensity descriptive scale to grade their pain.

### Data Analysis

Statistical analyses were completed by using version 11.5 of SPSS for Windows (SPSS Inc, Chicago, Ill). Descriptive statistics were computed for all variables. Interrater reliability was examined. Weighted  $\kappa$  coefficients were calculated for all assessments (T1-T9).<sup>29</sup> To test validity of the CPOT, we determined criterion and discriminant validity (Table 2). Criterion validity was examined by measuring the relationship between the CPOT scores and the patients' self-reports, the gold standard measure of pain. Analysis of variance was used to examine the differences between the intubated patients' self-reports of pain (yes or no) and the CPOT scores (assessments T4-T6). Also, Spearman correlations<sup>31</sup> were calculated between the

extubated patients' self-reports of pain intensity (ordinal descriptive scale) and the CPOT scores (assessments T7-T9). Finally, discriminant validity<sup>31</sup> was examined by performing paired  $t$  tests between assessments with the CPOT taken at rest and during positioning (T1 with T2, T4 with T5, and T7 with T8).

## Results

### Characteristics of the Sample

A total of 131 patients were approached for consent the day before surgery, and 117 (89%) agreed to participate in the study. Reasons for refusal were as follows: anxious about the surgery ( $n=9$  patients), not interested ( $n=3$ ), undecided ( $n=1$ ), and bad experience with research ( $n=1$ ). During the course of the study, 8 patients were excluded because of postoperative complications (hemorrhage, delirium, death), 3 because their surgery was canceled, and 1 because of extubation right after surgery. The final sample size was 105 patients enrolled during a 3-month period. Table 3 gives the demographic characteristics of the patients.

Anesthesia was similar for all patients, and all were receiving continuous infusions of propofol after surgery (mean dose 85.4 mg/h, SD 39.7 mg/h). For each patient, this medication was tapered off and stopped 1 to 3 hours after the patient's arrival in the ICU. Thus, all patients were receiving propofol during

**Table 3** Description of the study sample (n = 105)\*

Variable	Value	
Age, mean (SD)	60	(8)
Sex, No. (%) of patients		
Male	83	(79)
Female	22	(21)
Type of cardiac surgery, No. of patients (%)		
Coronary artery bypass graft	83	(79)
Valvular repair or replacement	11	(10)
Coronary artery bypass graft and valvular surgery	9	(9)
Interauricular/interventricular communication repair	2	(2)

\*All patients had sternal incisions.

the first testing period (ie, assessments T1-T3). All patients also were receiving continuous infusions of fentanyl when they were admitted to the ICU from surgery. The mean dosage of fentanyl decreased from 73.7  $\mu\text{g/h}$  (SD 21.8) at the first testing period to 50.7  $\mu\text{g/h}$  (SD 31.1) at the third testing period. Rarely, patients (n=4) received an intravenous bolus of fentanyl before positioning.

### Sample at the 3 Testing Periods

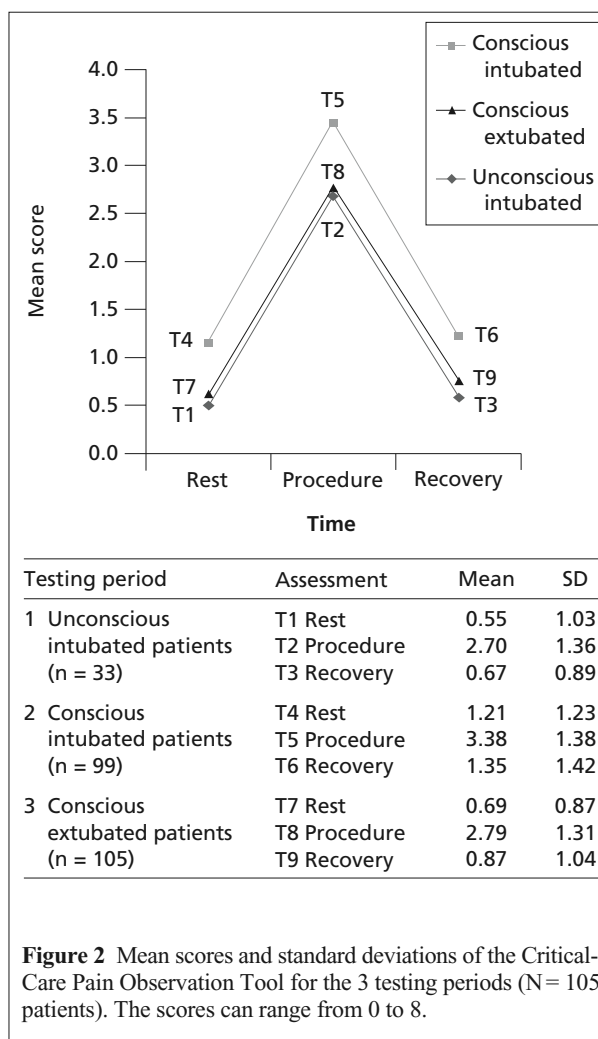
**First Testing Period.** For assessments T1 to T3, data were collected on 33 of the 105 intubated patients who were unconscious, a criterion for testing during this period. CPOT scores were higher during the positioning procedure (T2) than during rest (T1) or recovery (T3; Figure 2).

**Second Testing Period.** For assessments T4 to T6, data were collected on 99 of the awake 105 intubated patients. The remaining 6 patients were extubated before the completion of this testing period. Again, CPOT scores were higher during the positioning procedure (T5) than during rest (T4) or recovery (T6). Moreover, in this testing period, patients had the highest scores on the CPOT (Figure 2).

**Third Testing Period.** Finally, for assessments T7 to T9, all 105 patients were assessed after they were extubated. The CPOT scores were similar to those of the 2 previous testing periods (Figure 2).

### Interrater Reliability

Together, the principal investigator and the critical care nurse (C.G. and G.N.) completed the CPOT at all 9 assessments and were blinded to each other's scores. The sample sizes for interrater reliability differed for each time, reflecting the times when both were present.



**Figure 2** Mean scores and standard deviations of the Critical-Care Pain Observation Tool for the 3 testing periods (N = 105 patients). The scores can range from 0 to 8.

**Table 4** Weighted  $\kappa$  coefficients for each assessment from T1 to T9\*

Assessment	No. of patients	Weighted $\kappa$ coefficient
T1	12	0.83
T2	12	0.63
T3	14	0.85
T4	29	0.52
T5	33	0.85
T6	33	0.88
T7	34	0.62
T8	33	0.77
T9	34	0.71

\*Assessments made by using the Critical-Care Pain Observation Tool were independently completed by the principal investigator and the critical care nurse when both were present.

**Table 5** Differences in scores on the Critical-Care Pain Observation Tool according to patients' self-reports of pain in the second testing period (T4, T5, and T6)

Assessment	Patients' self-reports of pain: pain present or absent*	Scores		ANOVA	
		Mean	SD	F	df
T4	Yes, present (n = 53)	1.62	1.38	11.83 <sup>†</sup>	(1, 92)
	No, absent (n = 41)	0.78	0.85		
T5	Yes, present (n = 79)	3.65	1.31	22.18 <sup>†</sup>	(1, 95)
	No, absent (n = 18)	2.11	0.90		
T6	Yes, present (n = 54)	2.07	1.40	38.89 <sup>†</sup>	(1, 91)
	No, absent (n = 39)	0.49	0.88		

Abbreviation: ANOVA, analysis of variance.

\*Because of intermittent drowsiness postoperatively, 5 patients at T4, 2 at T5, and 6 at T6 were unable to give their self-reports of pain by nodding their heads.

<sup>†</sup> $P \leq .001$ . Alpha is adjusted to 0.01 because 3 comparisons were made on the same subjects.

Weighted  $\kappa$  coefficients were moderate to high at all assessments (Table 4).

### Criterion Validity

Mean CPOT scores according to patients' self-reports of the presence or absence of pain during the second testing period (ie, assessments T4-T6) and the analysis of variance are presented in Table 5. At each assessment in this testing period, CPOT scores were significantly higher for intubated patients reporting pain than for those who had no pain.

During the third testing period (ie, assessments T7-T9), mean pain intensity scores were significantly higher during the positioning procedure at T8 (2.01) than during rest at T7 (1.71) and recovery at T9 (1.40). Spearman correlations of 0.49, 0.59, and 0.40 ( $P \leq .001$ ) at T7 to T9 showed that the patients' self-reported pain intensity scores were moderately correlated with the CPOT scores.

### Discriminant Validity

At the 3 testing periods, CPOT scores were significantly higher during positioning than during the rest periods. Table 6 gives the results of the paired  $t$  tests.

### Discussion

Our findings validated the CPOT, which was developed specifically to assess pain in ICU patients. Interrater reliability was high for most assessments and moderate at T4. Payen et al<sup>19</sup> obtained a weighted  $\kappa$  coefficient of 0.74 when they compared behavioral pain scores between pairs of evaluators. A total of 46 nurses and nurse's aides, 1 physical therapist, and 1 physician participated in that study.<sup>19</sup> In our study, only 2 evaluators used the instrument, which is a limitation to the examination of interrater reliability, and results cannot be generalized to other ICU nurses.

*CPOT scores were associated with patients' self-reports of pain.*

When patients were intubated during the second testing period, CPOT scores differed significantly between those who reported pain and those who did not. Moreover, when patients were extubated during the third testing period, the higher a patient's self-report of pain was, the higher was the patient's score on the CPOT. These results are consistent with those of previous studies<sup>18,32</sup> in which self-reports of pain of patients in a postanesthesia care unit were moderately related to pain behaviors. Our results support the criterion validity of the CPOT because the indicators were tested against the most valid measurement of pain; that is, the patients' self-reports.

*CPOT scores were higher during painful procedures, lending support to its validity.*

Discriminant validity was supported by the finding that CPOT scores were higher during positioning than at rest in the 3 testing periods. Payen et al<sup>19</sup> also found higher behavioral scores during positioning than at rest in unconscious critically ill patients. Such results emphasize that pain behaviors are observable even if a patient cannot report pain.

Our study, however, is the first to document differences in pain behavior scores according to levels of activity during different states of consciousness and intubation: unconscious and intubated, conscious and intubated, and then awake and extubated. These results

**Table 6** Differences in scores on the Critical-Care Pain Observation Tool measured at rest before the procedure (T1, T4, and T7) and during the procedure (T2, T5, and T8)

Assessments	No. of patients	t	df
T1-T2	33	-9.01*	32
T4-T5	99	-12.07*	98
T7-T8	105	-15.96*	104

\*P < .001. Alpha is adjusted to 0.01 because 3 comparisons were made on the same subjects.

suggest that patients, whatever their levels of consciousness, may demonstrate pain behaviors in response to a nociceptive procedure. Whether a behavioral response to a noxious procedure is accompanied by perception of pain in an unconscious patient is unknown. Until there is evidence to the contrary, experts recommend that healthcare providers assume that unconscious patients may have pain, especially if behavioral responses to a known noxious stimulus occur. The experts<sup>33,34</sup> recommend that these patients be treated the same way as conscious patients when the patients are exposed to sources of pain.

*Experts recommend we assume that unconscious patients have pain, especially if behavioral responses to noxious stimuli occur.*

Indeed, in a study by Lawrence,<sup>35</sup> formerly unconscious patients revealed that they could hear, understand, and respond emotionally to what was being said while they were unconscious. In light of this finding, perhaps the CPOT can be used to assess pain in other populations of critical care patients. This hypothesis requires confirmation in future studies.

Interestingly, patients seemed to have higher CPOT scores when they were conscious and intubated than they did when they were unconscious or extubated. The presence of the endotracheal tube as a potential source of pain<sup>6,36</sup> for cardiac surgery patients, in addition to the sternal incision,<sup>5,8</sup> may help to explain these findings. Moreover, mechanical ventilation modes provided a positive inspiratory pressure to allow distribution of oxygen throughout the lungs.<sup>17</sup> This pressure may cause stretching of the sternal incision, which does not occur in nonsurgical patients, and which can be painful to some patients.

In our study, 65 conscious intubated patients had endotracheal suctioning while they were being posi-

tioned. However, when conscious intubated patients were positioned during assessment T5, 18 of them who did not report pain had high CPOT scores (mean 2.11, SD 0.90). Perhaps for these patients the positioning was a distressful or an uncomfortable experience<sup>1,9,37</sup> rather than a painful one. Also, the endotracheal tube may have caused coughing during the positioning procedure, leading to higher CPOT scores in the absence of reported pain. This finding suggests that behaviors observed by using the CPOT may be an indicator of more than pain. Further research is warranted to determine the sensitivity and specificity of the CPOT as a measure of pain.

*Behaviors observed by using the CPOT may indicate more than pain.*

We also found that CPOT scores were similarly low for both unconscious and conscious extubated patients. This result may have occurred because the patients were highly sedated while unconscious and may have been experiencing the residual effects of anesthesia.<sup>19</sup> Once extubated, they could have experienced less severe pain than they did when they were intubated.

Data collection in this study was completed in the 8 hours after surgery, a period when intermittent drowsiness can be expected. Previous studies<sup>7-9,12,20</sup> in which intubated patients provided self-reports of pain were conducted in periods varying from 12 to 72 hours after the end of surgery. Those patients might have had more time to recuperate from the residual effects of anesthesia than our patients did. In the study by Ferguson et al,<sup>5</sup> patients' self-reports of pain after coronary artery bypass graft surgery were collected more than 8 hours after the end of surgery, and 9 (21%) of 43 patients were unable to communicate their self-report of pain because of drowsiness. The occurrence of the same inability to communicate in the patients in our study is not surprising.

### Limitations

This study was not without limitations. First, data were collected by only 2 persons. More raters should be used in tests of interrater reliability in subsequent evaluations of the CPOT. Second, data could be collected for only 33 of the 105 patients while the patients were unconscious. Third, postoperative drowsiness led to missing data for some patients. Finally, cardiac surgery patients are a relatively healthy ICU group and may not represent most ICU patients, who are



much sicker. Future research on the effectiveness of the CPOT as a nonverbal measure of pain in other sicker ICU patients is warranted.

Despite these limitations, this study was innovative in several aspects. First, development of the CPOT was based on previous research of others as well as on descriptive data from 2 preliminary studies that led to selection of the behavioral indicators. Second, the relationship between intubated patients' self-reports of pain and behavioral indicators was explored for the second time. Finally, data were obtained from patients at different levels of consciousness.

Future research should be conducted to determine if CPOT scores can be used to differentiate pain from other conditions. Also, receiver operating characteristic curve analysis could be performed to examine the specificity and the sensitivity of the CPOT as a measure of pain. This further testing could substantiate the CPOT as a valid, reliable, and useful tool for measuring pain in critically ill patients who are unable to self-report.

## Conclusions

The CPOT had acceptable reliability and validity in this sample of cardiac surgery ICU patients. However, the tool needs to be further validated in different populations of critically ill patients. Appropriate pain assessment is an important part of quality care for critically ill patients, and use of validated measures of pain could aid in the evaluation of multidisciplinary pain management techniques for nonverbal critically ill patients.

## ACKNOWLEDGMENTS

Special thanks to Gaëlle Napert, the critical care nurse who contributed to data collection, and to François Harel, the statistician who reviewed the analyses. Thanks to all intensive care unit nurses and physicians for their support and collaboration in the performance of this study. Special thanks to Drs Jean Bussi res and Mathieu Simon for their valuable collaboration in the conception and the conduction of this study. Also, thanks to Celeste Johnston, RN, DEd, and Denise Li, RN, for their helpful comments on this article. Finally, thanks to all the patients who participated in this study. The research was performed at the Faculty of Nursing, Laval University, Quebec City, Quebec, Canada. This study was supported by a nursing fellowship research grant from the Heart and Stroke Foundation of Canada and a doctorate research grant from the Fondation de Recherche en Sciences Infirmi res du Qu bec.

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# Validation of a Behavioral Pain Scale in Critically Ill, Sedated, and Mechanically Ventilated Patients

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Assessing pain in critically ill patients, particularly in nonverbal patients, is a great challenge. In this study, we validated a behavioral pain scale (BPS) in critically ill, sedated, and mechanically ventilated patients. The BPS score was the sum of 3 subscales that have a range score of 1–4: facial expression, upper limb movements, and compliance with mechanical ventilation. Two assessors observed and scored pain simultaneously with the BPS at rest and during painful procedures. The psychometric properties of the BPS that were studied were reliability, validity, and responsiveness. We achieved 360 observations in 30 patients. The BPS was internally reliable (Cronbach  $\alpha = 0.72$ ). The intraclass correlation

coefficient to evaluate inter-rater reliability was high (0.95). Validity was demonstrated by the change in BPS scores, which were significantly higher during painful procedures, with averages of  $3.9 \pm 1.1$  at rest and  $6.8 \pm 1.9$  during procedures ( $P < 0.001$ ), and by the principal components factor analysis, which revealed a large first-factor accounting for 65% of the variance in pain expression. The BPS exhibited excellent responsiveness, with an effect size ranging from 2.2 to 3.4. This study demonstrated that the BPS can be valid and reliable for measuring pain in noncommunicative intensive care unit patients.

(Anesth Analg 2005;101:1470–6)

**A**ssessment and management of pain in critically ill patients have recently received increased attention (1–3). Scientific advances in understanding pain mechanisms, multidimensional methods of pain assessment, and analgesic pharmacology have improved pain management practices. However, pain assessment for critically ill patients, especially for nonverbal patients, continues to present a challenge for clinicians and researchers. Critically ill patients are unable to communicate effectively for several reasons, including tracheal intubation, reduced level of consciousness, restraints, sedation, and administration of paralyzing drugs (4–6).

Pain experts agree that a patient's self-report of pain intensity is the most valid measure (4). Unfortunately, most of the existing scales are designed for use with patients who can respond verbally to assessment commands. Consequently, pain management in nonverbal patients, such as elderly patients with cognitive impairment, is often guided by less precise and wholly

untested methods (7). Other methods, such as observational pain tools, must be used in a lieu of patients' self-reports of pain (8). The limited amount of data suggests that certain observable behaviors may be valid indicators of pain (9,10). Pain behaviors can be markers of the existence, intensity, and causes of pain. Indeed, observing pain behaviors is a common method of assessing pain, especially when patients are unable to verbalize.

Nevertheless, no pain scale comprising behavioral indicators has been validated in the intensive care unit (ICU), except the one developed by Payen et al. (11). The latter consisted of a behavioral pain scale (BPS), which was used to assess pain in patients who had undergone thoracic or abdominal surgery or who had been admitted for management of multiple trauma. However, its psychometric properties were insufficiently studied, and it has never been validated in a medical ICU. In addition, validation of any pain tool requires repeated tests of reliability, validity, and responsiveness across samples, settings, and observers. Therefore, the purpose of this prospective study, which sampled from a population of critically ill patients who were sedated and mechanically ventilated, was to validate Payen et al.'s (11) behavioral scale as a measure of pain using psychometric methods.

Accepted for publication April 6, 2005.

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DOI: 10.1213/01.ANE.0000182331.68722.FF

## Methods

The study was performed over a 6-mo period in a 12-bed ICU of the university teaching hospital Ibn Sina, Rabat, Morocco. The hospital ethical committee approved the study protocol, and because this observational study did not require any deviation from routine medical practice, informed consent was not required.

We included patients who were older than 16 yr, mechanically ventilated, sedated, and unconscious. Inclusion criteria were chosen because they precluded the use of an auto evaluation pain scale. Patients who were quadriplegic, receiving neuromuscular blocking medications, or had a peripheral neuropathy were excluded. Exclusion criteria were primarily selected to not include patients whose diseases or medications might compromise expression of the pain behaviors.

To assess pain intensity, we used the BPS described by Payen et al. (11). The BPS is based on a sum of three subscales: facial expression, upper limb movements, and compliance with mechanical ventilation (Table 1). Each subscale is scored from 1 (no response) to 4 (full response). Therefore, possible BPS scores range from 3 (no pain) to 12 (maximum pain).

In addition to the BPS scores, mean arterial blood pressure and heart rate were also collected, which were measured by multimodal monitors. These two hemodynamic variables were collected because previous studies had shown that increased heart rate and increased arterial blood pressure are the most frequent physiological indicators of pain noted by observing nurses (9).

The patients' sedation levels were assessed using the Ramsay scale (12). The Ramsay scale rates sedation level on a scale from 1 to 6, with higher levels indicating greater degrees of sedation. This instrument proved satisfactorily reliable and valid (13).

Sample characteristics were also recorded, including age, sex, Acute Physiology and Chronic Health Evaluation (APACHE) II score (14), and diagnosis categories. APACHE II score was calculated for the first 24 h.

For each patient, the BPS scores and the two physiological variables were collected three times a day by the various teams of nurses (morning team, afternoon team, and night team). Each team comprised four nurses and one nurse's aide. Assessments were made by two evaluators to measure the inter-rater agreement. The two assessors were the nurse and the physician in charge of the patient. They made their assessments simultaneously but without any communication between them. The assessors were not randomized, for reasons of convenience.

Evaluation of the BPS and the physiological variables was made at rest and during painful procedures to appreciate the BPS responsiveness. The two painful procedures chosen were tracheal suction and peripheral venous cannulation. They were selected because

their painful characters had been demonstrated in several previous studies (15-17) and because they were part of the routine care that was normally planned for the patients. No additional interventions or procedures were performed on the patients for the benefit of the study.

The assessments were done in the first 48 h after admission to the ICU. However, for patients who were not being ventilated at the time of their admission but who were ventilated later during their stay, the assessments were made in the first 48 h after mechanical ventilation began.

Twelve physicians and 16 nurses participated in the study. Before the beginning of the study, a training session was provided to teach assessors how to complete BPS, followed by a probation period (15 days), during which the BPS was tested on some patients ( $n = 4$ ).

Quantitative variables were expressed as mean  $\pm$  SD, and significance for all statistical tests was set at  $P = 0.05$ .

The sample size required for validation of the BPS was established using the precision of a coefficient, such as Cronbach  $\alpha$  or Intraclass Correlation Coefficient (ICC) (18). Thus, with a precision of Cronbach  $\alpha$  of  $0.90 \pm 0.05$  as an objective, and for a scale of 3 subscales, it was required to include 25-30 patients in the study.

The validation of an instrument measuring a subjective variable (like pain) requires a comparison with a "gold standard." Nevertheless, no pain scale has been validated in critically ill patients who were unable to communicate effectively because of the presence of artificial airways or underlying pathologies. Consequently, we had to validate the BPS with indirect arguments, which consisted of checking the psychometric properties of reliability, validity, and responsiveness.

Reliability refers to the lack of measurement error in a scale and includes internal consistency and inter-rater reliability. Internal consistency is an indication of how the items within a scale are interrelated. Cronbach  $\alpha$  is one method of assessing internal consistency (19). A high Cronbach  $\alpha$  value reflects high internal consistency. Generally, a value larger than 0.7 is regarded as satisfactory. Inter-rater reliability (or inter-rater agreement) is the ability of a new instrument to obtain similar measures with different assessors. It was assessed using the intraclass correlation coefficient (ICC) (20). Theoretically, the ICC can range from 0 (no agreement) to 1.0 (perfect agreement). Generally, a value larger than 0.8 is regarded as satisfactory (20). The ICC was calculated for the BPS and for each subscale of the BPS separately. A 95% confidence interval (CI) for the coefficient was derived.

Validity is the degree to which an instrument measures what it claims to measure (21). Validity was established in three ways: construct validity, change in

**Table 1.** The Behavioral Pain Scale (11)

Item	Description	Score
Facial expression	Relaxed	1
	Partially tightened (e.g., brow lowering)	2
	Fully tightened (e.g., eyelid closing)	3
	Grimacing	4
Upper limb movements	No movement	1
	Partially bent	2
	Fully bent with finger flexion	3
	Permanently retracted	4
Compliance with mechanical ventilation	Tolerating movement	1
	Coughing but tolerating ventilation for the most of time	2
	Fighting ventilator	3
	Unable to control ventilation	4

BPS scores during pain, and factor structure of the BPS.

Construct validity is the extent to which scores on a scale correlate with scores of other measures in predicted ways (21). We hypothesized that a significant correlation would be found between the BPS scores and the two physiological variables that were supposed to measure the same concept (pain). We also tested the correlation between the BPS and the Ramsay scale. Spearman nonparametric coefficients were used.

Change in BPS scores was assessed by comparing the BPS scores at rest and after painful procedures. We hypothesized that if the BPS really measures pain, the BPS scores should be much higher during painful procedures than while the patient is at rest. Wilcoxon paired tests (nonparametric) were used.

Furthermore, the factor structure of the BPS was extracted by performing exploratory principal components factor analysis. This is a statistical procedure that enables the underlying dimensions of a scale to be determined (21).

Responsiveness refers to an instrument's ability to detect important changes over time in the concept being measured, even if those changes are small (22). The magnitude of this property was assessed by the effect size. This coefficient is calculated by dividing the difference between the mean BPS scores at rest and during painful procedures by the SD of the mean scores at rest. The effect size is considered small if it is less than 0.2, moderate if it is near 0.5, and large if it is more than 0.8 (22).

## Results

The various teams assessed 38 patients. However, the assessments of 8 patients could not be included for 3 major reasons: (a) the patient died before the end of the assessments ( $n = 2$ ), (b) the presence of exclusion criteria (administration of neuromuscular blockade) ( $n$

**Table 2.** Principal Patient Characteristics

Age (y)	39 $\pm$ 19*
Sex: men/women ( $n$ )	18/12
APACHE II score	17 $\pm$ 7.8*
Diagnostic categories ( $n$ )	Nontraumatic coma (11) Acute intoxication (7) Respiratory failure (5) Sepsis (5) Status epilepticus (2)

\* Values expressed as mean  $\pm$  SD.

APACHE = Acute Physiology and Chronic Health Evaluation.

= 3), and (c) an incomplete or incorrect collection of data ( $n = 3$ ).

Thirty patients were included. The principal patient characteristics are presented in Table 2. Each patient was assessed three times a day (morning, afternoon, and night), by two observers (a physician and a nurse), and at two different times (at rest and during painful procedures). Thus, the various teams achieved 360 observations (30 patients  $\times$  2 observers  $\times$  2 different times  $\times$  3 times per day). Realization of a complete assessment usually required 3-4 min.

All patients were sedated with midazolam in continuous infusion except one patient who received thiopental (status epilepticus). The mean amount of midazolam administered was 5.6  $\pm$  2.5 mg/h. The Ramsay scale had an average value of 3.9  $\pm$  1.6. For analgesia, the drug frequently used was morphine, also in continuous perfusion. The mean amount of morphine administered was 3  $\pm$  0.7 mg/h.

Change in physiological variables is shown in Table 3. There was a significant increase in both hemodynamic variables during painful procedures. The amplitude of this increase was 10.7% for heart rate and 2.6% for mean arterial blood pressure.

Cronbach  $\alpha$  values indicated that the BPS had good internal consistency (Cronbach  $\alpha = 0.72$ ). ICC to evaluate the inter-rater agreement were high for all subscales of the BPS. For facial expression, ICC was 0.91 (95% CI, 0.88-0.93). For upper limb movements, ICC was 0.90 (95% CI, 0.87-0.92). For compliance with



**Table 3.** Physiological Variables at Rest and During Painful Procedures

	Rest	Painful procedures	P-value
Heart rate (bpm)	103 ± 22	114 ± 23	<0.001
Mean arterial blood pressure (mm Hg)	77 ± 26	79 ± 27	0.042

Values expressed as mean ± SD.

mechanical ventilation, ICC was 0.89 (95% CI, 0.85–0.92). ICC for the total score of the BPS was 0.95 (95% CI, 0.94–0.97). These values showed excellent inter-rater agreement. We also compared the BPS scores obtained by the three teams of caregivers. There was no significant difference (Table 4).

No significant correlation was found between the BPS scores and the physiological variables for variability. The correlation coefficients were  $r = 0.16$  ( $P = 0.13$ ) for heart rate and  $r = -0.02$  ( $P = 0.84$ ) for mean arterial blood pressure. When the correlation between the BPS scores and Ramsay scale was investigated, as expected, a significant negative correlation emerged ( $r = -0.432$ ;  $P < 0.001$ ). The higher the sedation level, the lower the BPS scores (Fig. 1).

BPS scores obtained at rest and during painful procedures appear in Table 5. The scores were significantly greater during painful procedures than at rest and did not differ between the two categories of painful procedures (tracheal suction and peripheral venous cannulation). Moreover, all subscale scores were significantly higher during painful procedures.

Using exploratory principal components factor analysis, we found a large first factor, which accounted for 65% of the variance in pain expression, with strong correlation of the subscales with this factor, including coefficients of 0.90 for facial expression, 0.85 for upper limb movements, and 0.64 for compliance with mechanical ventilation. Table 6 shows the correlation matrix between the subscales of the BPS. The 3 subscales were significantly correlated (all  $P < 0.001$ ), with a high correlation between facial expression and upper limb movements ( $r = 0.70$ ) and moderate correlations between compliance with mechanical ventilation and the 2 other subscales ( $r = 0.40$  with facial expression and  $r = 0.29$  with upper limb movements).

The effect size for responsiveness was large for the three subscale scores and for the total BPS scores (Table 5). These results showed an excellent responsiveness and, consequently, the excellent ability of the BPS to quantify change in clinical status and detect painful procedures.

## Discussion

This validation study showed that the BPS had good psychometric properties when used with critically ill

patients. In particular, the BPS showed a high inter-rater reliability (ICC = 0.95) and a satisfactory internal consistency (Cronbach  $\alpha = 0.72$ ). Validity of the BPS was demonstrated by a significant increase in BPS scores during painful procedures and by principal components factor analysis that identified a large first factor, which accounted for 65% of the variance in pain expression. Furthermore, the BPS exhibited an excellent responsiveness, suggesting that this is a powerful tool to detect the impact of painful stimulation in ICU patients.

Each of our patients was assessed by three teams of nurses to remove a possible bias caused by assessments being made by the same caregivers. Results showed that there was no significant difference among the evaluations made by the three teams.

At rest, theoretically, the BPS scores should be equal to 3, indicating the absence of pain. However, the mean BPS scores, which were near 4, suggest the possibility of preexisting background pain before any procedure was performed. Indeed, our patients, like all ICU patients, are subjected to a multitude of painful constraints, including various tubes (nasogastric and endotracheal), central and arterial lines, wrist restraints, etc. Another explanation could be that the amount of analgesic infusion was insufficient. This fact highlights the need for an instrument that can be used to titrate and adapt analgesia in critical care.

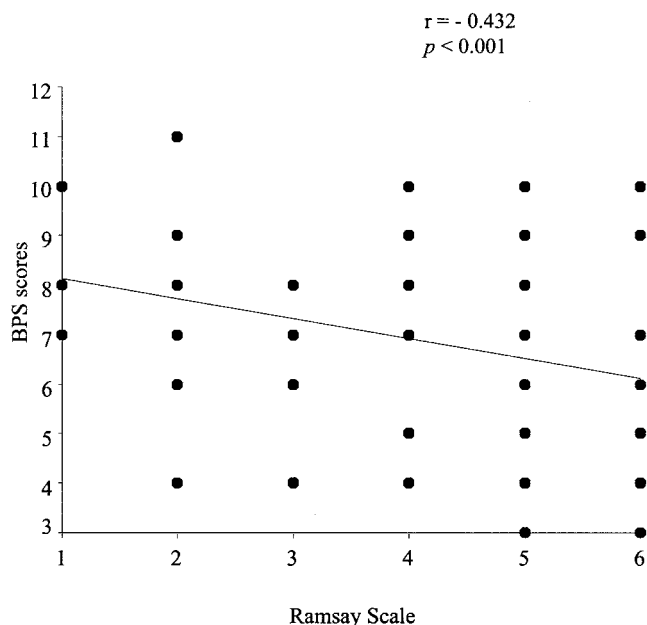
Pain is a stressor that produces a sympathetic stimulation (tachycardia, change in arterial blood pressure, diaphoresis, and change in pupillary size) (4,23). These physiological variations can help to detect pain among patients with impaired mental status (4,8,23,24). Puntillo et al. (9), in a study of patients having difficulties with verbal communication (mechanically ventilated or having been tracheally extubated less than four hours), showed that the most frequently noted physiological indicators of pain were increased heart rate and increased arterial blood pressure. In our study, heart rate and arterial blood pressure increased significantly during painful procedures, with the increase for heart rate measuring approximately 10%. These results coincide with the observations of clinicians who generally associate pain with a variation of from 10% to 20% in physiological variables (25). However, it is agreed that these physiological indicators lack specificity in the ICU and can be influenced by many medications (vasopressors,  $\beta$  adrenergic blockers, antiarrhythmics, sedative drugs, etc.) and pathological conditions (sepsis states, shock, hypoxia, and fear) (4). Moreover, no significant correlation was found among the BPS scores and the two physiological variables in our study. Unfortunately, the absence of an objective measure of pain in ICU patients limited the testing of construct validity. The study of Payen et al. (11) had the same results, and no published study with a sufficient level of scientific

**Table 4.** Behavioral Pain Scale Scores as Assessed by Three Nursing Teams

	Morning team	Afternoon team	Night team	P-value*
Rest	3.8 ± 1.2	3.7 ± 0.9	3.9 ± 1.2	0.44
Painful procedures	6.6 ± 1.7	6.8 ± 1.7	6.6 ± 2.2	0.46

Values expressed as mean ± SD.

\*Friedman test.

**Figure 1.** Correlations between the behavioral pain scale (BPS) and the Ramsay scale.

evidence has found a correlation among these physiological variables and pain (9).

However, the correlation between the BPS and Ramsay scale was negative and significant. The logical direction of the association is the higher the sedation level, the lower the ability to express painful behaviors.

In the present study, the BPS yielded a Cronbach  $\alpha$  of 0.72, thus fulfilling Nunnally and Bernstein's (26) criterion for satisfactory internal consistency. The inter-rater reliability of the BPS was found to be excellent (ICC = 0.95). This indicates that the BPS produces consistent scores from different assessors. Reliability is an essential property when caregivers are numerous, as in the ICU.

The BPS total and subscale scores were significantly higher during the procedures (Table 5). This change in BPS scores testifies to the instrument's capacity to detect and discriminate pain and provides the evidence that the BPS is a valid measure of pain. It is also important that all of the subscales changed, indicating that they all have the same ability to discriminate pain.

Principal factor analysis revealed that a large first factor was dominant and that the three subscales were strongly related to this factor, which means each of the

BPS subscales contributed to the overall pain assessment rating. The largest contributor was facial expression ( $r = 0.90$ ), followed by upper limb movements ( $r = 0.85$ ), and then compliance with mechanical ventilation ( $r = 0.64$ ). Furthermore, the positive significant correlation found among the three subscales demonstrates that they evaluate the same concept, which, in this case, was pain intensity.

This analysis has shown that behavioral indicators can be a valid and reliable measure of pain. Few studies have evaluated pain behaviors in the ICU (9,10,25). The most recent one (10) identified specific procedural pain behaviors such as grimacing, rigidity, wincing, shutting of eyes, verbalization, and clenching of fists. But in that study, the patients were awake and could measure their pain with a numeric rating scale. In fact, facial expression, which contributed most to the pain rating in our study, is a sign found in various works measuring both acute and chronic pain (25,27,28). Prkachin (27) has suggested that four facial actions carry the bulk of facial information about pain: lowering the brow, tightening and closing of the eyelids, wrinkling of the nose, and raising the upper lip. He has also provided evidence of the existence of a universal facial language of pain. The facial scales, which are especially useful for measuring pain in infants and children, highlight the value of this type of signal (4,23,29). Pediatric scales also rely on upper limb movements as a measure of pain (23,29). In our study, upper limb movements contributed as much as facial expression to the pain rating. Compliance with mechanical ventilation, adapted from the Comfort scale (11), had a moderate but effective contribution to pain assessment. The reason could be that this subscale might be affected by some factors unrelated to pain, such as hypoxemia, bronchospasm, and mucous plugging, which can lead to coughing and some fighting of the ventilator.

In addition to these psychometric properties, the BPS showed good feasibility, in as much as the average time of assessment was only four minutes. The short time required will make the BPS suitable for everyday clinical use.

This study has two limitations. First, one aspect of the validation process has not been addressed, namely the criterion validity (validity of the BPS in comparison with another validated pain scale). We could have compared the BPS to subjective rating of the level pain by an independent rater (a nurse) on a visual analog

**Table 5.** Behavioral Pain Scale (BPS) Total Scores and BPS Subscale Scores at Rest and During Painful Procedures, with the Effect Size

	Rest	Painful procedure	P*-value	Effect size
BPS subscales				
Facial expression				
Morning team	1.2 ± 0.6	2.6 ± 1	<0.0001	2.3
Afternoon team	1.1 ± 0.25	2.8 ± 1.1	<0.0001	6.8
Night team	1.2 ± 0.3	2.7 ± 1.2	<0.0001	5
Upper limb movements				
Morning team	1.1 ± 0.2	2 ± 0.7	<0.0001	4.5
Afternoon team	1 ± 0.2	1.9 ± 0.8	<0.0001	4.5
Night team	1.2 ± 0.5	1.9 ± 0.9	<0.0001	1.4
Compliance with mechanical ventilation				
Morning team	1.5 ± 0.6	2 ± 0.9	<0.046	0.8
Afternoon team	1.6 ± 0.6	2.1 ± 0.9	<0.005	0.8
Night team	1.5 ± 0.5	2 ± 0.9	<0.006	1
BPS total				
Morning team	3.8 ± 1.2	6.6 ± 1.7	<0.0001	2.3
Afternoon team	3.7 ± 0.9	6.8 ± 1.7	<0.0001	3.4
Night team	3.9 ± 1.2	6.6 ± 2.2	<0.0001	2.2

\* Wilcoxon paired test.

**Table 6.** Correlation Matrix Among the Items of the Behavioral Pain Scale

	Facial expression	Movements of upper limbs	Compliance with mechanical ventilation
Facial expression	1		
Movements of upper limbs	0.70	1	
Compliance with mechanical ventilation	0.41	0.29	1

Values shown represent Spearman nonparametric correlation coefficients; all correlations were statistically significant at  $P < 0.001$ .

scale (VAS). However, apart from the BPS, no other validated instrument has been developed to measure the level of pain in mechanically ventilated ICU patients, and the VAS has never been validated in such patients. In addition, a number of studies have found that from 35% to 55% of nurses under-rate patient pain when using the VAS (4). This precludes any analysis of criterion validity in which the new instrument would be compared to a reference instrument.

The second limitation of our study is that the sample of critical care patients observed was small. Future studies will have to include more patients.

We conclude that the present study provides evidence that the BPS has good psychometric properties. This instrument might prove useful to measure pain in uncommunicative critically ill patients and to evaluate the effectiveness of analgesic treatment and adapt it. Further studies are required to determine whether the use of this scale can really improve management of pain in the critical care setting.

The authors gratefully acknowledge all the nurses and physicians who participated in this study, Dounia Benzarouel for her assistance with data collection, and Younès Lahrech and Khalil Zakari for their help during the writing of this manuscript.

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Assinatura do(a) Autor(a) Principal: Daniela Filipe Almeida da Cunha

Local e data: Ponte, Agosto 2011

A ser completado pela revista

Publicado no Número \_\_\_\_\_, Ano \_\_\_\_\_



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**ANEXO III**

**APRESENTAÇÃO DO ARTIGO:**

**INSTRUMENTOS DE AVALIAÇÃO DA DOR EM PESSOAS**

**COM ALTERAÇÃO DA CONSCIÊNCIA:**

**UMA REVISÃO SISTEMÁTICA**



## **Instrumentos de avaliação da dor em pessoas com alteração da consciência: uma revisão sistemática**

Pain assessment instruments for patients with impaired consciousness: a systematic review

Los instrumentos de evaluación del dolor en personas con alteración de la consciencia: una revisión sistemática

### **Resumo**

Nos doentes com alteração do estado de consciência a comunicação está comprometida e a auto-avaliação da dor não é possível, dificultando a avaliação da mesma por parte de profissionais de saúde tornando-se fundamental a utilização de escalas de avaliação da dor válidas e confiáveis.

Esta revisão tem como finalidade analisar o potencial de utilização clínica das escalas existentes para avaliação da dor em doentes com alteração da consciência.

A revisão bibliográfica realizada teve como base dois motores de busca e três bases de dados, cobrindo o período de Janeiro de 2005 a Junho de 2011. Um total de 654 títulos e resumos foram analisados, 16 documentos foram seleccionados para revisão de texto completo, dos quais 8 trabalhos foram incluídos na revisão. Três repositórios locais foram visitados e apenas 1 documento foi incluído na revisão.

Foram identificadas sete diferentes escalas de avaliação da dor usadas em doentes com alteração da consciência. Apenas uma escala incluiu indicadores fisiológicos e comportamentais, as restantes incluem apenas indicadores comportamentais. A escala BPS obteve a melhor classificação podendo ser implementada nestes doentes.

São necessárias mais pesquisas acerca dos efeitos da utilização destes instrumentos de avaliação da dor na prática clínica (e suas implicações).

**Palavras-chave:** dor, avaliação, adulto, alteração da consciência.

### **Abstract**

In patients with impaired consciousness, pain self-assessment is impracticable and communication is compromised, therefore challenging assessment by health care professionals. This causes the use of valid and trustful scales to become fundamental.

The present study aims to evaluate the clinical potential of the existent scales for the assessment of pain in patients with impaired consciousness.

The literature review comprehends the time frame from January of 2005 to June of 2011 based on two search engines and three databases. A total of 654 abstracts and titles were analyzed, 16 papers were selected for a full body revision of which 8 comprise within the present review. Three university archives were visualized and only 1 paper was included herein.

Seven distinct assessments of pain scales were identified in patients presenting impaired consciousness. Only one of the scales took into account physiological and behavioral indicators, whereas the remaining others included solely behavioral indicators. The BPS scale obtained the highest rating, thus turning its implementation possible in these patients. More research, concerning the effects of the use of assessment of pain tools in clinics and their implications, is required.

**Keywords:** pain, assessment, adult, impaired consciousness.

## **Resumen**

En los pacientes con alteración del estado de consciencia la comunicación está comprometida/afectada y la autoevaluación del dolor no es posible, dificultando la evaluación del dolor por parte de los profesionales de la salud resultando fundamental la utilización de escalas de evaluación del dolor validas y fiables.

Esta revisión tiene como finalidad analizar el potencial de utilización clínica de las escalas existentes para la evaluación del dolor en los pacientes con alteración de la consciencia.

La revisión bibliográfica realizada tuvo como base dos herramientas de búsqueda y tres bases de datos, cubriendo el periodo de Enero de 2005 a Junio de 2011. Fueron analizados un total de 654 títulos y resúmenes, 16 documentos fueron seleccionados para revisión de texto completo, de los cuales 8 trabajos fueron incluidos en la revisión. Fueron visitados 3 archivos universitarios y solo 1 documento ha sido incluido en la revisión.

Se identificaron 7 escalas diferentes de evaluación del dolor usadas en los pacientes con alteración de la consciencia, solo 1 escala incluye indicadores fisiológicos y del comportamiento, las demás incluyen solo indicadores del comportamiento. La escala BPS ha obtenido la mejor clasificación pudiendo ser aplicada en estos pacientes. Son necesarios más estudios sobre los efectos de la utilización de estos instrumentos de evaluación del dolor en la práctica clínica (y sus implicaciones).

**Palabras clave:** dolor, evaluación, adultos, alteración de la consciencia.

## **Introdução**

A avaliação da dor, pela sua relevância clínica, tem sido uma das preocupações centrais de todos aqueles que se dedicam a este domínio problemático. Segundo Pereira e Sousa (1998, p. 77) “mensurar a dor tem sido um grande desafio para aqueles que almejam controlar adequadamente tão complexa experiência”.

A mensuração da dor no meio clínico ganhou maior atenção nos últimos tempos. Estudos de mensuração e sua análise evidenciam que os instrumentos unidimensionais ainda prevalecem na avaliação da experiência dolorosa. Porém, o desafio de se considerar a multidimensionalidade dessa experiência tem levado muitos investigadores a elaborar e

utilizar instrumentos mais precisos e abrangentes nas suas pesquisas (Pereira e Sousa, 1998).

Vários autores defendem que a principal recomendação na avaliação da dor é que esta seja relatada pelo próprio doente (Odhner *et al.*, 2003; Gélinas *et al.*, 2004; Aissaoui *et al.*, 2005; Herr *et al.*, 2006 e Juarez *et al.*, 2010). No entanto, existem várias situações e condições em que o doente (cliente) não se encontra capaz de comunicar eficazmente, nomeadamente, em termos verbais, a intensidade da sua experiência dolorosa. Aqui, destacam-se múltiplos motivos possíveis, dos quais merecem destaque as alterações cognitivas, as lesões cerebrais, as situações de internamento em unidades de cuidados intensivos, onde a sedação e/ ou o recurso a suporte ventilatório comprometem significativamente aquela competência de interacção. No contexto do ambiente onde exercemos a nossa actividade profissional – uma unidade de Traumatologia Crânio – Encefálica -, as alterações a que aludimos são muito frequentes, pelo que a comunicação (verbal) dos doentes está comprometida e auto-avaliação da dor, podemos dizê-lo, é uma impossibilidade (Aissaoui *et al.*, 2005; Herr *et al.*, 2006; Kabes *et al.*, 2009 e Juarez *et al.*, 2010). As alterações da consciência são o principal obstáculo com que nos deparamos no nosso quotidiano clínico, com as “naturais” consequências, em termos de avaliação da dor dos nossos doentes.

Na maior parte dos estudos que estão disponíveis, há referência a doentes com compromissos do estado de consciência, muitas vezes por indução medicamentosa e não por causa directa da patologia ou trauma. Assim, a definição de consciência apresenta-se aqui como uma questão fundamental.

Laureys (2010) no seu estudo define estado vegetativo como a abertura dos olhos, espontânea ou induzida por estimulação, sem qualquer sinal de consciência, em que todos os movimentos observados são (apenas) reflexos.

Na Classificação Internacional para a Prática de Enfermagem - CIPE®, versão 2.0 – (International Council of Nurses, 2011), classificação adoptada como *standard* em Portugal e que faz parte das terminologias reconhecidas pela Organização Mundial de Saúde (OMS), consciência é definida como uma “Resposta mental a impressões resultantes de uma combinação dos sentidos, mantendo a mente alerta e sensível ao ambiente exterior”.

Todavia, para mitigar a dificuldade na interpretação uniforme do nível de consciência dos doentes, a Escala de Comas de Glasgow (ECG) tem constituído o referencial e “*golden standard*” utilizado para objectivar a avaliação da consciência.

A ECG é uma escala altamente confiável, que permite a avaliação do nível de consciência, aspecto crucial numa avaliação neurológica; baseando-se na observação de três parâmetros: i) melhor resposta verbal; ii) melhor resposta motora e, iii) resposta ocular. O *score* máximo de 15 corresponde a uma pessoa desperta e totalmente alerta e o *score* mínimo de 3 a um doente em coma profundo, não reactivo (Baptista, 2003).

Geralmente, considera-se que o doente está consciente quando este consegue cumprir comandos simples, como apertar a mão e largar, pôr a língua de fora, fechar os olhos com força, entre outros. Assim, a capacidade do doente para responder a tais comandos simples é considerada como prova de consciência (Laureys, 2010). Ora, pelo exposto, os compromissos da consciência, muito frequentes na nossa prática clínica levantam-nos várias dificuldades da interacção com os doentes; facto que, dada a dimensão fenomenológica da experiência de dor, nos desafia a procurar estratégias suficientemente competentes para procurar objectivar tal sensação.

A dor é uma experiência subjectiva por definição, e os doentes com compromisso do estado de consciência são incapazes de comunicar de forma consistente as suas experiências e as suas respostas comportamentais a estímulos nociceptivos são frequentemente difíceis de interpretar (Boly *et al.*, 2008).

De acordo com Gélinas e colaboradores (2006) é, ainda, desconhecido se em doentes com graves compromissos da consciência, a resposta comportamental a um estímulo doloroso é acompanhado pela percepção da dor. No entanto e até prova em contrário, peritos recomendam que os prestadores de cuidados de saúde assumam que os pacientes “inconscientes” têm dor, especialmente se as respostas comportamentais a estímulos dolorosos estiverem presentes.

Assim, e segundo Herr e colaboradores (2006), quando não é possível avaliar com certeza a presença da dor e, tendo em conta as recomendações para gestão da dor, deveremos sempre realizar a prova terapêutica (teste analgésico) nestes doentes. Num estudo realizado por Lawrence em 1995 (citado por Gélinas *et al.*, 2006), doentes “ex-inconscientes” revelaram poder ouvir, compreender e responder emocionalmente ao que lhes era dito enquanto estavam com compromisso da consciência. Assim, estes doentes devem ser tratados da mesma forma que os doentes conscientes, quando expostos a estímulos potencialmente dolorosos.

Admite-se que existe dor quando há uma patologia (causa) que a motive, bem como, quando o doente está sujeito a procedimentos, nomeadamente de enfermagem, que podem ser considerados dolorosos, tais como aspiração de secreções, posicionamentos, mudanças de roupa, inserção e remoção de catéteres e quando o doente tem restrição ao leito. Algumas condições médicas incluindo, isquemia, infecções, inflamação, edema, distensão, imobilidade, incisões, feridas e a utilização de instrumentos médicos invasivos e não invasivos também são factores desencadeantes de dor (Stanik-Hutt, 2003 e Pudas-Tahka *et al.*, 2009).

A existência de traduções/ indicadores objectivos da dor reúne consenso entre os investigadores desta área. Vários autores sugerem o comportamento corporal e sinais fisiológicos como indicadores objectivos e observáveis da presença de dor, quando o doente

não está capacitado para a comunicar (Odhner *et al.*, 2003; Gélinas *et al.*, 2004; Aissaoui *et al.*, 2005; Herr *et al.*, 2006 e Juarez *et al.*; 2010).

Neste contexto, é importante salientar a diferença entre a classificação da intensidade da dor baseada no relato dos doentes, e a avaliação da dor através de escalas comportamentais, que somente se fundamentam em características ou traduções objectivas e clinicamente observáveis, que podem apenas indicar a presença ou aparente ausência de dor (Kabes *et al.*, 2009).

Melzack, citado por Gélinas e colaboradores (2004), divide as traduções ou indicadores de dor em duas categorias: a) não observáveis/subjectivos e b) observáveis/objectivos. Os não observáveis/subjectivos são os componentes sensoriais, emocionais e cognitivos da dor (sensorial: características como intensidade, localização, qualidade, factores agravantes ou de alívio da dor; emocionais: sentimentos e emoções associadas à experiência da dor; e cognitivos: significado atribuído à dor). Os observáveis/objectivos são os componentes fisiológicos e comportamentais de dor. No estudo efectuado por Gélinas e colaboradores (2004), os autores concluíram que os indicadores subjectivos não eram documentados pelos profissionais de saúde, sendo utilizados maioritariamente os indicadores observáveis. O estudo de Marques (2009), realizado em unidades de cuidados intensivos de um hospital central do Porto, revelou uma realidade caracterizada por uma “quase ausência” de avaliação sistemática da dor dos doentes internados, em que nem os indicadores “mais” objectivos eram utilizados, para efeitos de inferência diagnóstica, focada na dor.

O aumento da tensão arterial e frequência cardíaca são os sinais fisiológicos mais frequentemente associados à dor aguda. Entre os indicadores fisiológicos reconhecidos encontram-se: os cardiovasculares, tais como alterações da tensão arterial e frequência cardíaca; os respiratórios: alteração da frequência respiratória, diminuição da saturação de oxigénio; os cerebrais: aumento da PIC (Pressão Intra Craniana) e redução da perfusão cerebral (Odhner *et al.*, 2003; Gélinas *et al.*, 2004; Aissaoui *et al.*, 2005 e Juarez *et al.*, 2010). Aissaoui e colaboradores (2005), assim como Odhner e colaboradores (2003), especificam ainda: a mudança no tamanho pupilar, palidez, rubor, transpiração, náusea e vômitos. Admite-se que os indicadores fisiológicos podem ser mais facilmente avaliados e documentados em Cuidados Intensivos, devido à monitorização constante. Existem opiniões contrárias à sua utilização, já que alguns autores defendem que não são sinais específicos da existência de dor podendo, as suas alterações serem resultantes de medicação ou da patologia adjacente, pelo que a sua relevância necessita de ser mais explorada (Odhner *et al.*, 2003; Gélinas *et al.*, 2004 e Juarez *et al.*, 2010).

Relativamente aos indicadores comportamentais, Gélinas e colaboradores (2004) identifica e descreve: os movimentos corporais (agitação), a *compliance* com o ventilador (tossir, “morder” o tubo), os sinais neuromusculares (aumento do tónus muscular, tremores, rigidez

muscular), outros meios de comunicação (tentativa de falar, recorrência à mímica, sinalização com a cabeça), expressões faciais, reacções aos exames físicos, qualidade do descanso, estado neurológico (colaboração, reacção à dor, orientação).

Odhner e colaboradores (2003) especificam e expõem como potenciais indicadores de dor, no espaço dos cuidados intensivos: o “ranger” de dentes, enrugar a testa, chorar, movimentos lentos e cautelosos, inquietação, reflexos de retirada, debater-se, movimentos rítmicos, dar pontapés, tensão muscular, massajar ou esfregar áreas de corpo e também o assumir determinadas posições ou posturas, ditas de defesa.

Os indicadores de comportamento como expressões faciais, movimentos corporais, postura rígida e *compliance* com o ventilador, quando relacionados com a dor aguda podem ser bem documentados pelos enfermeiros, fruto da observação dos doentes (Gélinas *et al.*, 2004).

Sendo a dor uma experiência essencialmente subjectiva, o relato e descrição do doente é de extremo valor clínico. No entanto, não é possível obter auto-relatos em pacientes “não-comunicativos” ou com compromissos significativos da comunicação verbal (Schnakers *et al.*, 2010). Baseado neste pressuposto, e tendo em conta os indicadores fisiológicos e comportamentais, foram sendo criadas e testadas escalas de avaliação da dor para doentes incapazes de comunicar verbalmente ou compromissos graves dessa capacidade, como é o caso dos doentes com os quais lidamos no nosso quotidiano.

Deste modo, na tentativa de perceber a utilidade clínica de cada escala construída para avaliar a dor, em doentes com alterações da consciência, vários foram os autores que desenvolveram, testaram, validaram e/ ou traduziram escalas. Não obstante a sua importância, são descritas várias limitações nestes estudos ao longo da literatura consultada, pelo que, a utilização destes instrumentos na prática clínica é restrita, sendo que as principais limitações referidas incluem amostras reduzidas, falta de validação, confusão na definição de comportamentos (por exemplo, movimentos do corpo e rigidez muscular) e o uso de observações dependentes (Gélinas *et al.*, 2006).

Pelo exposto ao longo do enquadramento da problemática fica clara a nossa intenção de evoluir num estudo focado na avaliação da dor em doentes com alterações da consciência, como é o caso daqueles que assistimos no nosso contexto de exercício profissional.

## **Objectivos**

O objectivo deste estudo é analisar o potencial de utilização clínica das escalas disponíveis para efeitos de avaliação da dor, em doentes com alteração da consciência.

As principais questões que nortearam o nosso percurso foram:

- Quais as escalas existentes para avaliar a dor em doentes com alteração da consciência?
- Que tipo de indicadores estas ferramentas incluem?

- Que tipo de propriedades psicométricas estas ferramentas possuem?

## Metodologia

Para a obtenção de documentos, foi realizada uma pesquisa sistemática da literatura publicada entre Janeiro 2005 a Junho de 2011. Utilizaram-se os motores de buscas EBSCO e PUBMED. Um total de 654 títulos e resumos foram analisados, segundo os critérios de inclusão e exclusão, sendo seleccionados para revisão de texto completo 16 documentos, dos quais 9 foram aceites para o estudo, estando incluídos nas seguintes bases de dados: Academic Search Complete, CINAHL e Medline.

Foi, ainda, efectuada pesquisa nos repositórios de teses de mestrado e teses de doutoramento da Faculdade de Medicina da Universidade do Porto (FMUP), da Escola Superior de Enfermagem do Porto (ESEP) e do Instituto de Ciências Biomédicas Abel Salazar (ICBAS) onde, mais frequentemente, os enfermeiros realizam formação pós – graduada. Destes repositórios foi seleccionado apenas um documento; tratando-se de uma tese de mestrado. A revisão bibliográfica foi efectuada apenas pelo investigador principal.

Os descritores utilizados (nos idiomas Inglês e Português) e as suas combinações encontram-se no Quadro 1.

**Quadro 1 - Descritores utilizados.**

<b>Descritores utilizados</b>	Pain, scale, nonverbal, adult, unconscious, behavioral, assessment, critical-care, observation, tool, intensive care, coma, impaired consciousness, measurement, brain-injured patients, nociception, sedated.
<b>Combinações</b>	Behavioral and pain and scale/ Behavioral and pain and assessment and scale/ Critical-Care and Pain and Observation and Tool/ Nonverbal and Adult and Pain and Assessment and Scale/ Pain and adult and scale and intensive care/ Pain and unconscious and scale and adult/ Pain and coma and scale and adult/ Pain and coma/ Pain and nociception/ Pain and impaired consciousness/ Scale and pain and unconscious/ Measurement and pain and unconscious/ Pain and brain-injured patients/ Pain and non-verbal patients/ Nociception and unconscious/ Pain assessment and nonverbal/ Pain and sedated.

## Critérios de Inclusão

Para serem incluídos, os estudos teriam de cumprir os seguintes critérios: descrever uma escala de avaliação da dor para adultos com compromissos da comunicação, incapazes de relatar a sua experiência de dor; documento escrito em Inglês ou Português, disponível em texto integral e ser de acesso gratuito; data de publicação entre Janeiro de 2005 e Junho de 2011. Todos os estudos que não cumpriram cumulativamente estes critérios foram excluídos do estudo.

## Avaliação da qualidade dos instrumentos de avaliação da dor identificados

O estudo a que nos propusemos teve como principal propósito explorar o potencial de utilização, no contexto onde exercemos funções, das escalas e instrumento de avaliação da

dor identificados. Assim, tivemos necessidade de definir um conjunto de critérios a serem considerados para efeitos da referida apreciação.

Os critérios utilizados para este exercício foram adaptados da metodologia definida por Zwakhalen e colaboradores, em 2006, num estudo de revisão sistemática, cujos objectivos foram: identificar as escalas para avaliação da dor em idosos com demência severa; analisar as suas propriedades psicométricas e a respectiva utilidade clínica. A mesma metodologia foi também utilizada por Pudas-Tahka e colaboradores (2009), numa abordagem com a mesma intenção geral. A metodologia a que recorremos, tendo por base um conjunto de critérios que iremos descrever, visa atribuir um *score* global a cada instrumento; *score* esse que, quanto mais alto, mais recomenda a utilização do instrumento. Todavia, a sua interpretação não dispensa a leitura dos *scores* parciais que são atribuídos a cada um dos critérios.

A metodologia utilizada centra-se nos seguintes critérios: a) origem dos termos; b) viabilidade; c) tempo para aplicação; d) validade de conteúdo; e) validade de constructo; f) validade de critério; g) consistência interna ou homogeneidade e; h) concordância entre avaliadores (Quadro 2). Cada um dos critérios apresentados recebe uma pontuação numa escala ordinal de 0-2, com um total de 0-16. Como vimos e se percebe do descrito, quanto maior a pontuação, melhor a qualidade da escala.

## Resultados

Os nove trabalhos seleccionados foram submetidos aos critérios de inclusão e aprovados. Nestes 9 trabalhos encontram-se representadas sete escalas de avaliação da dor. De acordo com a revisão da literatura efectuada, existem escalas dirigidas adequadas às características dos doentes que assistimos na nossa prática clínica. Foi-nos possível identificar sete (7) escalas de avaliação da dor dirigidas àqueles doentes. No Quadro 3 são apresentadas os instrumentos identificados.

Relativamente às escalas apresentadas no quadro 3, parece-nos importante salientar alguns aspectos relevantes, que contribuem para a compreensão da utilidade das mesmas.

A escala **FLACC (Face, Legs, Activity, Cry, Consolability)** inclui uma variedade de indicadores que são associados à dor em crianças, a adultos com comprometimento cognitivo, e adultos em estado crítico. Esta ferramenta é amplamente reconhecida, é utilizada nos Estados Unidos, tendo sido traduzida em várias línguas, incluindo francês, chinês, sueco, italiano e português (Voepel-Lewis *et al.*,2010).

A escala **BPAS (Behavioral Pain Assessment Scale)** foi criada por Merkel e colaboradores em 1997 e adaptada por Campbell em 2000 (cit. por Marques, 2009). É recomendada e encontra-se protocolada no *Johns Hopkins University School of Medicine* (Baltimore – Estados Unidos da América EUA) para doentes internados em unidades de cuidados



intensivos (Marques, 2009). Esta escala foi validada e traduzida para português por Marques em 2009.

**Quadro 2 – Critérios usados no julgamento de qualidade das escalas.**

<b>Critério</b>	<b>Descrição</b> (Fortin, 2009 e Gélinas <i>et al.</i> , 2006)	<b>Pontuação</b> (Zwakhalen <i>et al.</i> , 2006)
<b>Origem dos termos</b>	Este item de avaliação pretende avaliar se a escala foi especialmente elaborada para doentes com alteração da consciência ou se os itens que as compõem foram modificados de outra(s) escala(s), como por exemplo, através de escalas de avaliação da dor em crianças ou adultos com demência.	2: especialmente elaborada para uso em doentes com alteração da consciência; 1: itens foram modificados ou adaptados de outra(s) escala(s); 0: itens com origem em outras populações.
<b>Viabilidade</b>	Pretende determinar as possibilidades de sucesso da escala, apurando se é viável ou não a sua utilização. Reporta a facilidade de utilização.	2: escala é curta, de fácil aplicação, inclui instruções e interpretação da pontuação; 1: escala é de fácil aplicação mas não inclui instruções ou interpretação da pontuação; 0: escala é complexa.
<b>Tempo para aplicação</b>	Interfere na sistematização dos cuidados, reflectindo a sua importância numa lógica que alia a organização do tempo e a satisfação das necessidades da prestação de cuidados ao doente. Critério que complementa a viabilidade, reportando a tempo médio dispendido no preenchimento da escala.	2: menos de 5''(minutos); 1: 6''<10''(minutos); 0: >11'' (minutos).
<b>Validade de Conteúdo</b>	Refere-se ao carácter representativo dos enunciados utilizados no instrumento para medir o conceito ou o domínio em estudo. Critério que visa clarificar até que ponto os enunciados do instrumento representam o conjunto dos aspectos envolvidos ou que compõem o fenómeno. Em síntese, pretende-se avaliar se os conteúdos ou itens da escala são ou não representativos do domínio que pretendem medir; se cobrem todas as dimensões do fenómeno.	2: a escala abrange indicadores comportamentais e fisiológicos; 1: a escala abrange indicadores comportamentais ou indicadores fisiológicos; 0: não abrange nem indicadores comportamentais nem fisiológicos.
<b>Validade de Constructo</b>	Refere-se à propriedade das medidas diferenciadas. Está ligada ao critério, à capacidade do instrumento para medir o conceito ou o constructo definido teoricamente, mostrando que a estrutura do instrumento está de acordo com a teoria subjacente. Utiliza, muitas vezes, o método dos grupos (condições) de contraste (grupos que sabemos que são diferentes e que deveriam obter pontuações diferentes numa mesma escala). Frequentemente, baseia-se nas avaliações da dor em repouso e durante o procedimento doloroso.	2: diferencia bem entre presença de dor e ausência de dor; 1: diferencia moderadamente bem; 0: não diferencia.
<b>Validade de Critério</b>	Refere-se à propriedade dos <i>scores</i> obtidos com a utilização da escala estarem correlacionados com um critério externo e bem conhecido, o que reforça a sua validade. Normalmente, neste particular é utilizada a matriz de correlação da escala de avaliação da dor em apreço com outro instrumento de medida (da dor), muitas vezes tomado com " <i>golden standard</i> ". Com frequência é utilizada a técnica da "validade simultânea".	2: correlação alta (>0,60); 1: correlação moderada (0,40 - 0,60); 0: correlação baixa (<0,40).
<b>Consistência Interna ou Homogeneidade</b>	Medida de fidelidade ou confiabilidade de um instrumento de medida, que indica a concordância existente entre todos os enunciados individuais que constituem o instrumento de medida, referindo-se à homogeneidade de um conjunto de enunciados que servem para medir diferentes aspectos do mesmo conceito (reporta-se, em rigor, à ligação entre enunciados da escala de medida). Quanto mais os enunciados estão correlacionados, maior é a consistência interna do instrumento, assentando no princípio de que o instrumento só mede um conceito – unidimensional. A técnica mais utilizada para apreciar o grau de consistência interna é o cálculo do coeficiente de Alfa ( $\alpha$ ) de <i>Cronbach</i> , que varia entre 0.00 e 1.00 (um valor alto indica uma grande consistência interna). Este procedimento é muito usado em observações de um único avaliador por "caso".	2: Alfa <i>Cronbach</i> >0,70; 1: Alfa <i>Cronbach</i> 0,60> alfa <0,70; 0: Alfa <i>Cronbach</i> <0,60.
<b>Confiabilidade entre avaliadores</b>	É uma medida de fidelidade ou confiabilidade que avalia a consistência (concordância) com a qual dois ou mais avaliadores (independentes entre si) concordam nas suas medições/observações, relativamente a um fenómeno, neste caso, a dor. O coeficiente K é a medida mais utilizada, traduzindo a proporção de respostas nas quais os diferentes avaliadores concordaram.	2: coeficiente de confiabilidade > 0,80; 1: 0,60 < coeficiente de confiabilidade <0,80; 0: coeficiente de confiabilidade <0,60.

**Quadro 3 - Escalas de avaliação da dor para doentes inconscientes e/ou entubados.**

Nome Escala	Autor/ Data	Constituição Básica / Itens	Pontuação
<b>FLACC: Face, Legs, Activity, Cry, Consolability Instrument</b>	Merkel <i>et al.</i> (1997)	Face (0-2), Pernas (0-2), Actividade (0-2), Choro (0-2) e Conforto (0-2).	0 (sem dor) a 10 (máximo de dor).
<b>BPAS: Behavioral Pain Assessment Scale</b>	Merkel <i>et al.</i> (1997) e adaptada por Campbell, M. (2000)*	Expressão facial (0-2), Inquietude (0-2), Tônus muscular (0-2), Vocalização (0-2) e Consolabilidade (0-2).	0 (sem dor), 1-3 (dor suave), 4-5 (dor moderada) e superior a 5 (dor severa) e 10 pontuação máxima.
<b>BPS: Behavioral Pain Scale</b>	Payen <i>et al.</i> (2001)	Expressão facial (1-4), Movimentos dos membros superiores (1-4) e Conformidade com a ventilação mecânica (1-4).	3 (sem dor) a 12 (máximo de dor).
<b>NVPS: Nonverbal Adult Pain Assessment Scale</b>	Odhner <i>et al.</i> (2003), revista por Wegman (2005)**	Face (0-2), Actividade (movimento) (0-2), <i>Guarding</i> (0-2); Sinais fisiológicos I (sinais vitais) (0-2), Respiração (0-2) e Sinais fisiológicos II (outros sinais) (0-2).	0 (sem dor) a 12 (máximo de dor).
<b>CPOT: Critical Care Pain Observation Tool</b>	Gélinas <i>et al.</i> (2006)	Expressão facial (0-2), Movimentos do corpo (0-2), Tensão muscular (0-2), Tolerância ao ventilador (se o doente entubado) ou Vocalização (se o doentes extubado) (0-2).	0 (sem dor) a 8 (máximo de dor).
<b>BPS-NI: Behavioral Pain Scale-non intubated</b>	Chanques <i>et al.</i> (2009)	Expressões faciais (1-4), Movimentos dos membros superiores (1-4) e Vocalizações (1-4).	3 (sem dor) a 12 (máximo de dor).
<b>NCS: The Nociception Coma Scale</b>	Schnakers <i>et al.</i> (2010)	Resposta motora (0-3), Resposta verbal (0-3), Resposta visual (0-3) e Expressões faciais (0-3).	0 (sem dor) a 12 (máximo de dor).

\*cit. por Marques, F. (2009)

\*\*cit. por Kabes *et al.* (2009)

Baseada nos resultados do estudo de Puntillo e colaboradores (1997, cit. por Cade, 2008), a **BPS (Behavioral Pain Scale)** foi elaborada por Payen e colaboradores (2001) para avaliar a dor em doentes críticos; é a ferramenta mais amplamente testada. Esta escala já foi utilizada em vários estudos nomeadamente: Chanques e colaboradores (2009), Marques (2009), Cade (2008), Young e colaboradores (2006) e Assaoui e colaboradores (2005). Trata-se de um instrumento recomendado pela *American Society for Pain Management Nursing (ASPMN)*, para avaliação da dor em doentes entubados e/ou inconscientes (Gélinas *et al.*, 2011). Esta escala foi validada e traduzida para português por Marques em 2009.

Elaborada por Odhner e colaboradores em 2003, a **NVPS (Nonverbal Adult Pain Assessment Scale)** é baseada na *FLACC Scale*, comportando indicadores comportamentais e fisiológicos (Cade, 2008), estando recomendada para avaliação da dor em doentes internados em unidades de cuidados intensivos, sedados, em coma, e/ou ventilados (Kabes *et al.*, 2009).

Desenvolvida para doentes adultos em estado crítico, ventilados ou não ventilados, por Gélinas e colaboradores (2006), a escala **CPOT (Critical Care Pain Observation Tool)** foi até ao momento testada num total de 255 doentes de cuidados intensivos, com diagnóstico pós-operatório, médico ou de trauma (Gélinas *et al.*, 2011). Esta escala foi traduzida para português por Marques em 2009. Esta escala também é recomendada pela *American Society for Pain Management Nursing (ASPMN)* para avaliação da dor em doentes entubados e/ou inconscientes (Gélinas *et al.*, 2011).

Ao encontro do objectivo de agilizar a avaliação da dor em doentes críticos não entubados e incapazes de transmitir a dor, Chanques e colaboradores (2009) adaptaram a escala *Behavioral Pain Scale*, chamando-lhe de **BPS-NI (Behavioral Pain Scale-Non Intubated)**. Nesta adaptação (Chanques *et al.*, 2009) foi introduz o domínio “*vocalization*” em substituição de “*compliance with ventilation*”. As vocalizações foram descritas como gemidos, gritos, queixas verbais de dor e uso de palavras de protesto. Neste estudo e após a realização de testes, esta escala mostra ser válida e confiável para avaliar a dor nestes doentes (Chanques *et al.*, 2009).

A escala **NCS (Nociception Coma Scale)** surge na tentativa de solucionar a dificuldade de aceder a respostas comportamentais em doentes com lesão cerebral (Schnakers *et al.*, 2010). Em doentes “não-comunicativos” não é possível obter auto-relatos, assim a dor é entendida como nocicepção e definida como um evento potencial (ou actual), que causa dano nos tecidos, traduzida e codificada por receptores nociceptivos (Schnakers *et al.*, 2010). Assim, a detecção de sinais comportamentais de nocicepção, em doentes em recuperação do coma, representa um importante desafio médico e ético (Schnakers *et al.*, 2010). Esta escala (NCS) constitui, na opinião dos autores o primeiro passo para uma melhor avaliação e controlo da dor, em doentes com alterações de consciência, constituindo uma ferramenta clínica sensível para a avaliar em doentes com lesão cerebral (Schnakers *et al.*, 2010). O interesse clínico real desta escala é acompanhar os doentes que não têm possibilidade de comunicar. Através da avaliação e acompanhamento de comportamentos do doente, a NCS permite o seguimento do mesmo e do seu tratamento, a fim de evitar efeitos sedativos, bem como sub-utilização de analgésicos (Schnakers *et al.*, 2010).

## **Discussão dos resultados**

O estudo que realizámos permitiu-nos identificar um conjunto alargado de instrumentos de avaliação da dor, dirigidos a doentes com o perfil daqueles que cuidamos numa unidade de trauma neurológico. Quer isto significar, desde logo, que o fenómeno da dor poderá ser alvo de um processo de monitorização e acompanhamento mais sistemático e objectivo. Na última década tem sido realizado um vasto esforço pela comunidade científica, no sentido de desenvolver e testar ferramentas capazes de nos auxiliar no diagnóstico e, por consequência, tratamento da dor de doentes internados em unidades de tratamento intensivo.

As escalas que foram identificadas incluem parâmetros ou indicadores capazes de, com maior objectividade, traduzir a presença e até a intensidade da dor, nos doentes com compromissos graves da consciência, sedados e com suporte ventilatório. Aspectos como a expressão facial, o tónus muscular, os sinais vitais ou a adaptação ao ventilador, a par das vocalizações, constituem traços comuns dos parâmetros incorporados nas diferentes escalas.

A aplicação da metodologia utilizada para avaliar a robustez (psicométrica) dos diferentes instrumentos não nos permitiu afirmar da existência de uma “escala perfeita”, na medida em que nenhum dos instrumentos obteve a pontuação máxima (16 valores) na nossa apreciação. Assumimos, a par dos diferentes autores consultados, que são necessários mais estudos para aumentar a nossa base de conhecimento sobre os referidos instrumentos. No entanto, os resultados apurados abrem-nos excelentes perspectivas, apontando para instrumentos que, desde já, podem ser incorporados na nossa prática clínica.

Da aplicação dos critérios definidos, os nossos resultados demonstraram que a escala BPS recebeu a melhor pontuação com 14 pontos (num máximo de 16), e as BPS-NI, FLACC e NVPS foram aquelas que evidenciaram os segundos melhores *scores*, com as pontuações de 12 pontos. A escala NCS, embora seja a mais recente, obteve um *score* global de 11 pontos. Os *scores* apurados são influenciados pela quantidade e, essencialmente, natureza dos estudos disponíveis. Por exemplo, a escala BPS beneficia do facto de existirem bastantes estudos onde é incluída, o que permite uma avaliação mais completa e a obtenção de pontuações nos múltiplos parâmetros da nossa análise. Quer isto significar que as escalas com *scores* globais mais baixos também têm mérito, apesar de necessitarem de mais estudos para avaliar as suas propriedades psicométricas.

No que respeita à origem dos itens incorporados nas diferentes escalas constatámos que a maioria das escalas em apreço contempla itens especialmente elaborados para doentes sedados ou com alterações da consciência.

Quanto ao critério de viabilidade, nenhuma das escalas inclui instruções de interpretação, o que, não as distinguindo, poderá derivar do facto de serem fáceis de utilizar. Embora seja possível encontrar instruções de utilização destas escalas noutras pesquisas efectuadas acerca das mesmas, nos artigos pertencentes aos resultados não encontramos descrição desta matéria.

Na mesma linha, quanto ao tempo dispendido na sua aplicação, das escalas em que este parâmetro está disponível (BPS, BPS-NI e NCS), podemos verificar que o seu potencial de utilização clínica é alto, na medida em que as escalas consomem pouco tempo, para efeitos da observação dos diferentes itens e respectivo registo. Em menos de cinco (5) minutos é possível monitorizar a dor dos nossos doentes.

No que se inscreve no âmbito da validade das escalas em apreço no nosso estudo, constatamos que os parâmetros: validade de constructo e validade de critério revelam, globalmente, valores muito bons, para as diferentes escalas. Este facto atesta do potencial de utilização destes instrumentos na nossa prática clínica. A validade de conteúdo, muito influenciada pela origem dos itens, é mais robusta na NVPS.

Em termos de fidelidade, verificamos coeficientes de consistência interna bastante apreciáveis, o que atesta a homogeneidade das escalas em que este parâmetro foi avaliado. Em paralelo, os valores apurados para a concordância entre diferentes avaliadores (quando disponível) são bastante robustos, o que atesta o facto das medidas obtidas não serem dependentes dos observadores (clínicos), facto que vem reforçar as possibilidades de utilização em larga escala deste tipo de instrumentos.

### **Limitações da pesquisa**

Reconhecemos que no nosso trabalho existem limitações que devem ser abordadas. Como em qualquer revisão sistemática, é possível que não tenhamos conseguido identificar alguns estudos relacionados com o tema, no entanto, tentamos minimizar esse facto realizando a busca de documentos em diferentes bases de dados.

Surge também como limitação do estudo o facto da revisão bibliográfica ter sido efectuada apenas por um investigador, facto que pode concorrer para erros “sujeito – dependentes”. A inexperiência do investigador principal, a este propósito, constituirá a principal limitação do estudo aqui relatado e sintetizado.

O facto de termos usado apenas literatura indexada e com texto completo disponível e gratuito, com restrição temporal (2005 a 2011), cria uma mancha “cinzenta”, relativa a eventuais documentos não indexados ou indexados sem texto completo disponível, onde poderão estar alguns artigos e relatórios com mérito e utilidade.

Uma vez que a nossa busca se limitou a incluir documentos em Português e Inglês, não foram incluídos outros hipotéticos estudos redigidos noutras línguas.

**Tabela 1 - Scores obtidos pelas diferentes escalas de avaliação da dor, submetidas ao instrumento de avaliação da sua qualidade.**

Ferramenta de avaliação / Fonte	BPAS Marques, F. (2009)	BPS Aissaoui <i>et al.</i> (2005) Marques (2009) Pudas-Tahka <i>et al.</i> (2009)	NVPS Kabes <i>et al.</i> (2009) Pudas-Tahka <i>et al.</i> (2009)	CPOT Gélinas <i>et al.</i> (2006)	BPS-NI Chanques <i>et al.</i> (2009)	FLACC Voepel- -Lewis (2010)	NCS Schnakers <i>et al.</i> (2010)
<b>Origem dos termos</b> 2: Especialmente elaborada para uso em doentes sedados ou com alteração da consciência; 1: Itens foram modificados; 0: Itens originados de outra população.	1 (modificada de uma escala de avaliação da dor para crianças – FLACC)	2	1 (modificada de uma escala de avaliação da dor para crianças – FLACC)	2	2 (BPS modificada)	2	2
<b>Viabilidade</b> 2: Escala é curta, de fácil aplicação, inclui instruções e interpretação da pontuação; 1: Escala é de fácil aplicação mas não inclui instruções ou interpretação da pontuação; 0: Escala é complexa.	1	1	1	1	1	1	1
<b>Tempo para aplicação</b> 2: <5"; 1: 6" < t < 10"; 0: > 11".	ND	2 Tempo para avaliação completa entre 3 - 4"	ND	ND	2 Tempo para avaliação completa entre 2 - 5"	ND	2 Tempo para avaliação completa entre 1 - 5"
<b>Validade de conteúdo</b> 2: A escala abrange indicadores comportamentais e fisiológicos; 1: A escala abrange indicadores comportamentais ou indicadores fisiológicos; 0: A escala não abrange nem indicadores comportamentais nem fisiológicos.	1 (indicadores comportamentais)	1 (indicadores comportamentais)	2	1 (indicadores comportamentais)	1 (indicadores comportamentais)	1 (indicadores comportamentais)	1 (indicadores comportamentais)
<b>Validade de constructo</b> 2: Diferencia bem entre presença de dor e ausência de dor; 1: Diferencia moderadamente bem; 0: Não diferencia.	2	2	2	2	2	2	2
<b>Validade de critério em relação a outras escalas</b> 2: Correlação alta (> 0,60); 1: Correlação moderada (0,40 - 0,60); 0: Correlação baixa (<0,40).	2 vs BPS (0,907)	2 vs BPAS (0,907)	2 vs FLACC (0,86)	ND	ND	2 vs CNPI (0,96) vs COMFORT (0,85)	2 vs NIPS (0,71) vs FLACC (0,69) vs CNPI (0,80) vs PAINAD (0,72)
<b>Consistência Interna ou Homogeneidade</b> 2: Alfa <0,70; 1: 0,60 > Alfa <0,70; 0: Alfa <0,60.	2 (0,89)	2 (0,72)	2 (0,78)	ND	2 (0,79)	2 (0,88)	ND
<b>Confiabilidade entre avaliadores</b> 2: Coeficiente de confiabilidade > 0,80; 1: 0,60 < coeficiente de confiabilidade < 0,80; 0: Coeficiente de confiabilidade < 0,60.	ND	2 (0,95) (0,82-0,94)	2 (0,90)	2 (0,52-0,88)	2 (0,82-0,89)	2 (0,96)	1 (0,61)
<b>Score global</b> (variação entre 0 e 16):	<b>9</b>	<b>14</b>	<b>12</b>	<b>8</b>	<b>12</b>	<b>12</b>	<b>11</b>

(**Legenda:** BPAS - Behavioral Pain Assessment Scale; BPS - Behavioral Pain Scale; NVPS - Non-Verbal Pain Scale; CPOT - Critical Care Pain Observation Tool; BPS - NI - Behavioral Pain Scale Non - Intubated; FLACC – Face, Legs, Activity, Cry, Consolability Behavioral Tool; NCS - Nociception Coma Scale; NIPS – Neonatal Infant Pain Scale; PAINAD - Pain Assessment In Advanced Dementia Scale; CNPI – The Checklist of Non-verbal Pain Indicators; ND – Não Disponível).

## **Conclusões**

A gama de instrumentos disponíveis para avaliar a dor em doentes com compromissos da consciência, sedados e/ ou com suporte ventilatório é apreciável. Neste quadro, avançarmos para a utilização sistemática e regular de um instrumento de monitorização da dor é algo que, para além de recomendável, se nos afigura como altamente viável no curto prazo. As pontuações parciais e o *score* global obtido pela BPS - Behavioural Pain Scale (Payen *et al*, 2001 e Puntillo *et al*, 1997, cit. por Cade, 2008), a par do facto desta escala estar traduzida para português (Marques, 2009) sugere-nos a sua utilização no imediato, no quadro da unidade onde exercemos funções.

Da mesma forma, as escalas BPS-NI, NVPS e FLACC também obtiveram boas pontuações no estudo por nós efectuado. A BPS-NI e NVPS padecem do inconveniente de não terem sido publicados estudos de tradução destas escalas para a língua portuguesa, no entanto, a escala FLACC foi traduzida/adaptada culturalmente e validada para o contexto português, utilizada em crianças por Batalha *et al*. (2009).

A utilização de instrumentos de avaliação da dor pode ser vista como uma estratégia de promoção da qualidade dos processos de diagnóstico e, por essa via, do tratamento e controlo da dor. É esta finalidade que perseguimos, tendo em vista, por esta via, contribuir para a melhoria da qualidade dos cuidados de enfermagem.

Para além das implicações práticas que resultam deste nosso estudo, no futuro próximo, entendemos adequado evoluir no desenvolvimento de um projecto de investigação que, à escala do nosso serviço, nos permita estudar as características da dor e o impacto das intervenções de enfermagem nesta experiência dos doentes.

## **Financiamento**

A origem dos recursos teve como fonte de financiamento ao trabalho, a atribuição da Bolsa de Formação *Isabel Correia Levy* pela Associação Portuguesa de Cuidados Paliativos, há qual deixamos desde já o nosso agradecimento.

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